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(54) **SPINE IMPLANT WITH A DEFELCTION ROD SYSTEM ANCHORED TO A BONE ANCHOR AND METHOD**

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***A61B 17/70*** (2006.01)
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(52) **U.S. Cl.** ..... **606/254**

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See application file for complete search history.

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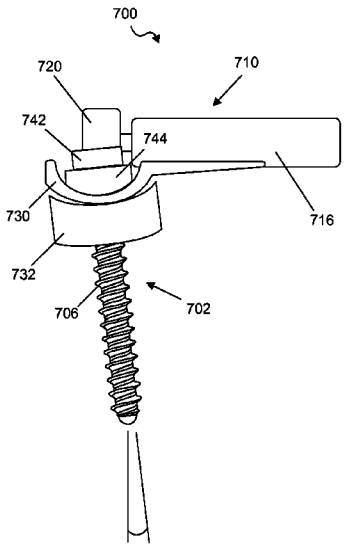
(57) **ABSTRACT**

A dynamic stabilization, motion preservation spinal implant system includes a deflection rod system implant. The system is modular so that various constructs and configurations can be created and customized to a patient.

**20 Claims, 31 Drawing Sheets**



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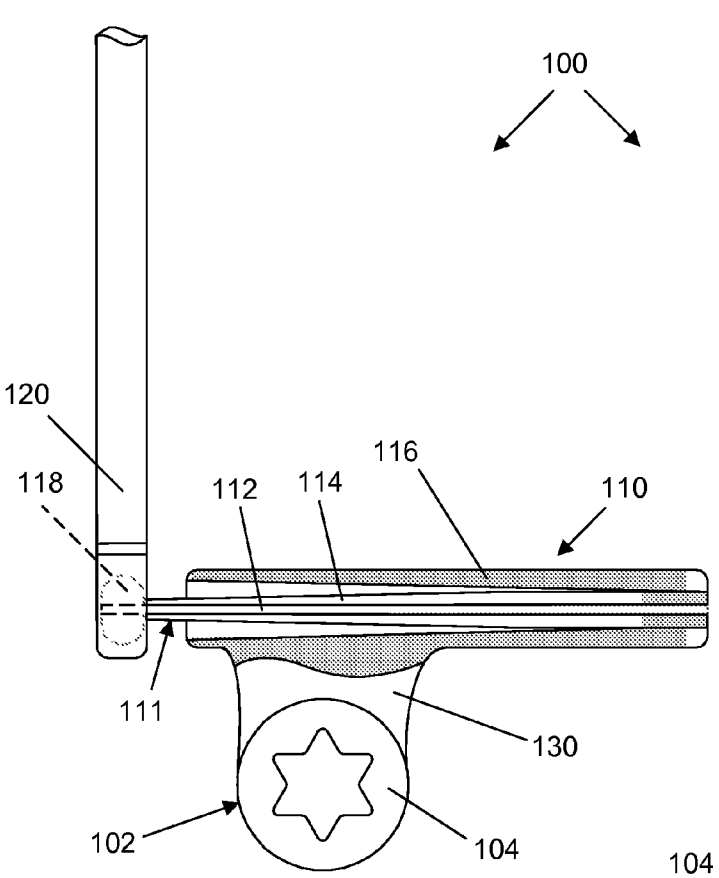
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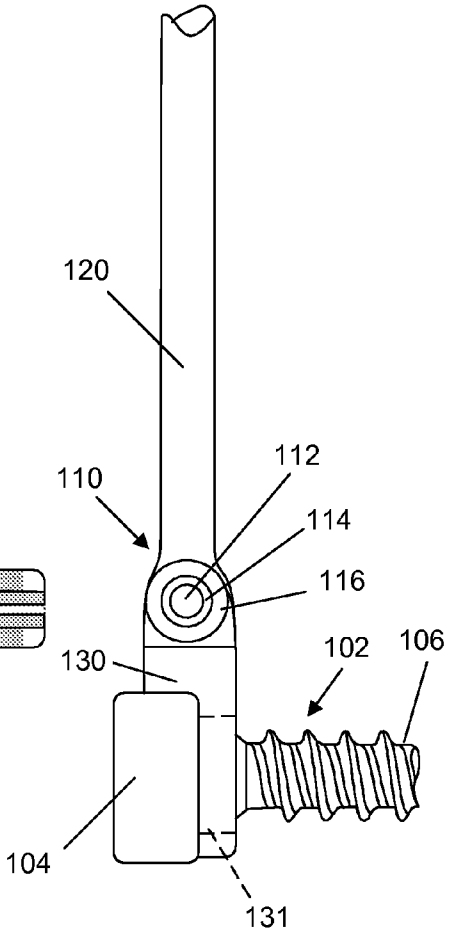
102
104

FIG. 1A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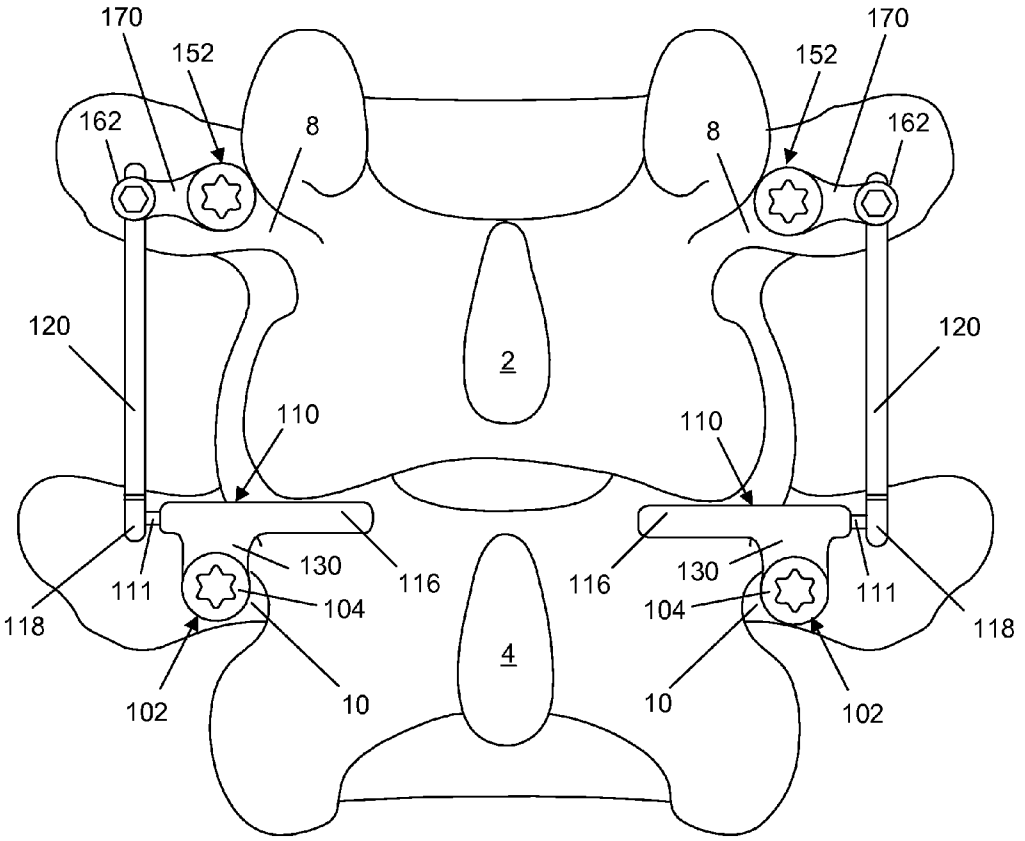
131

FIG. 1B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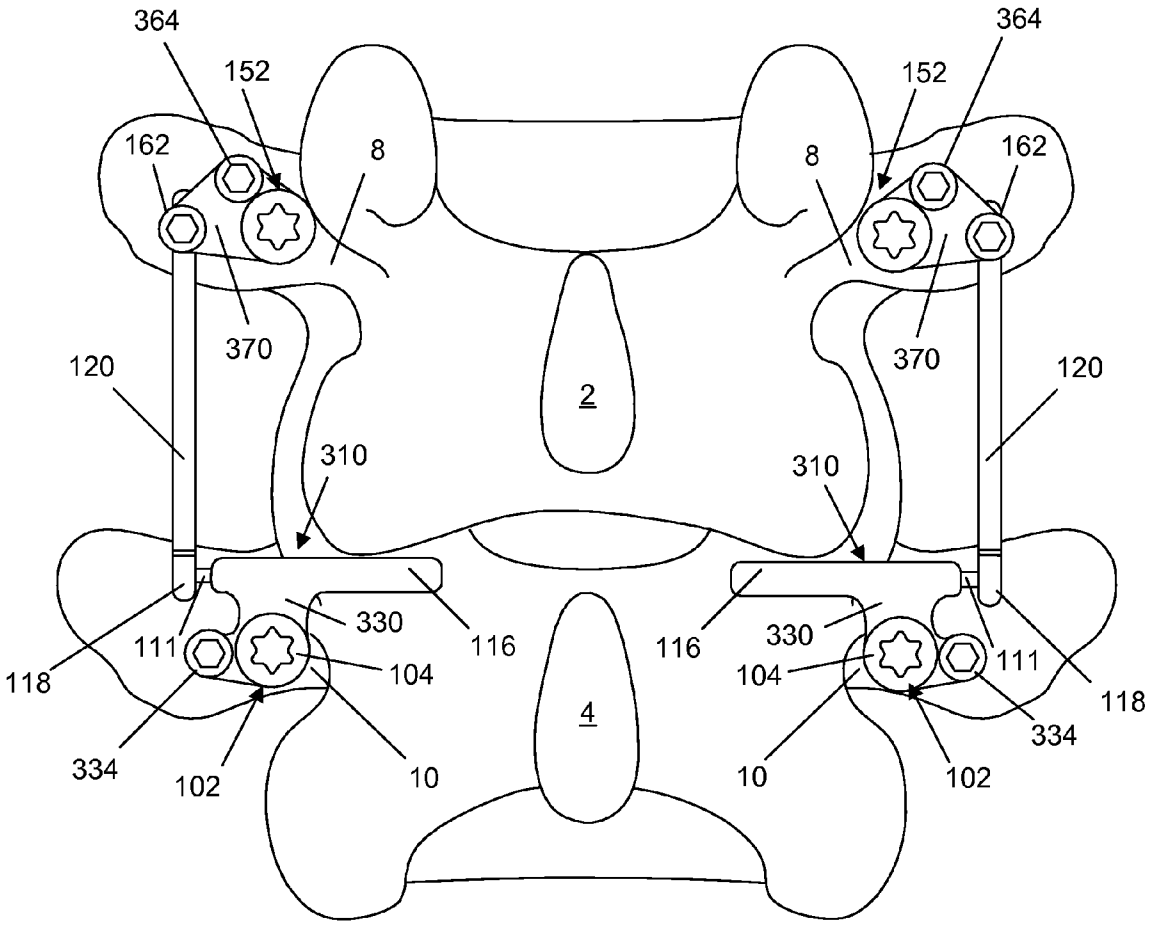
120
110
111
130
116
104
118
102
10
2
4
170
152
162
8
120
110
116
130
104
111
118
10
102

FIG. 2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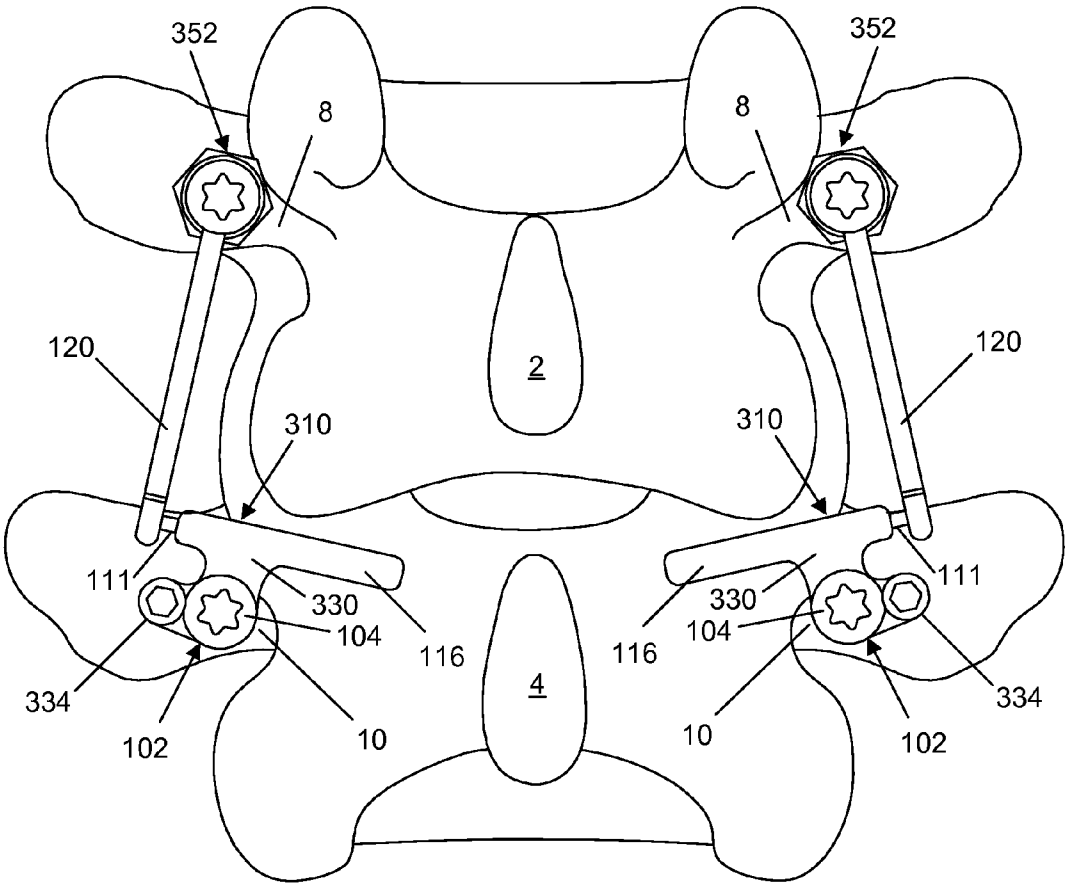
370
120
310
330
116
111
118
104
334
102
10

FIG. 3A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352
8
8
120
120
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111
330
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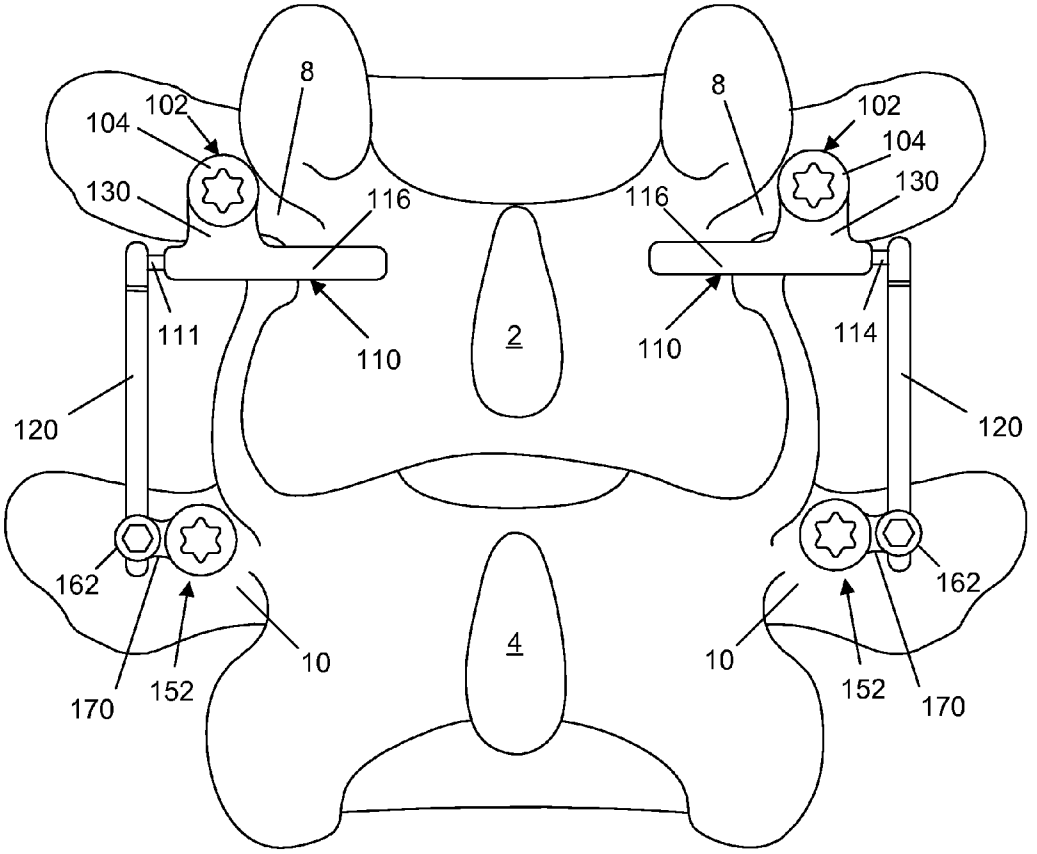
104
104
116
116
4
334
334
102
102
10
10

FIG. 3B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8
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104
102
104
130
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114
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120
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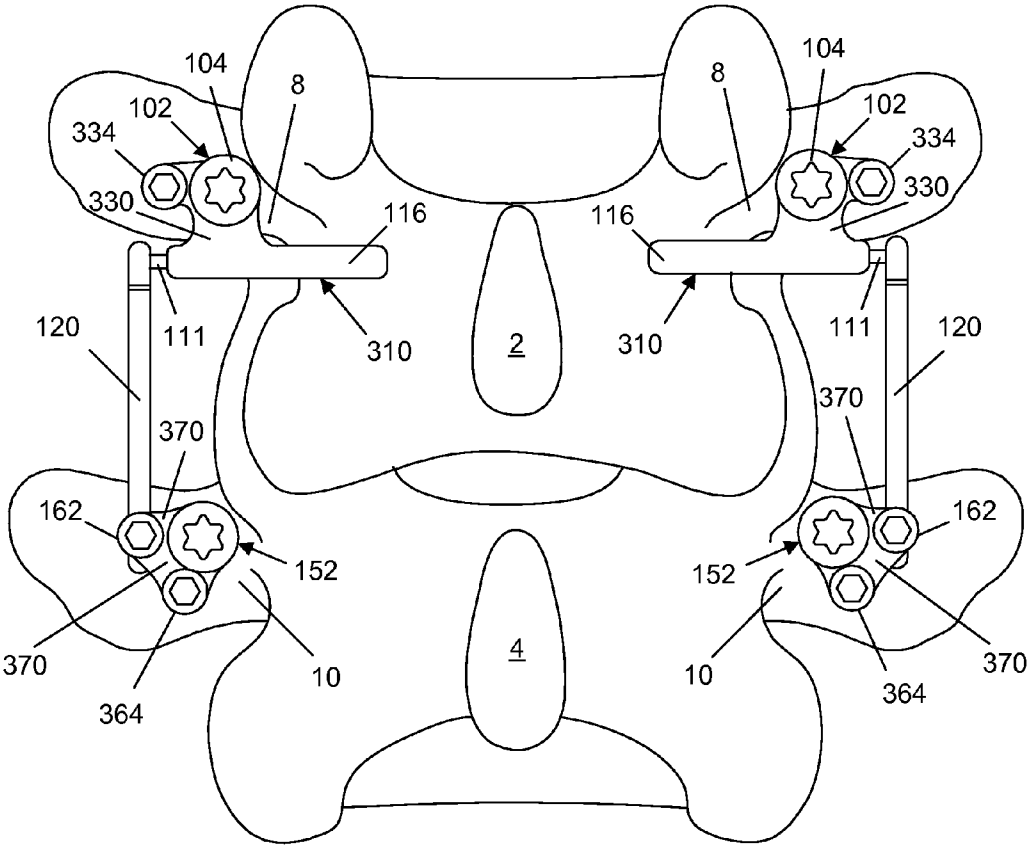
10
10
4
152
152
170
170

FIG. 4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120
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162
152
370
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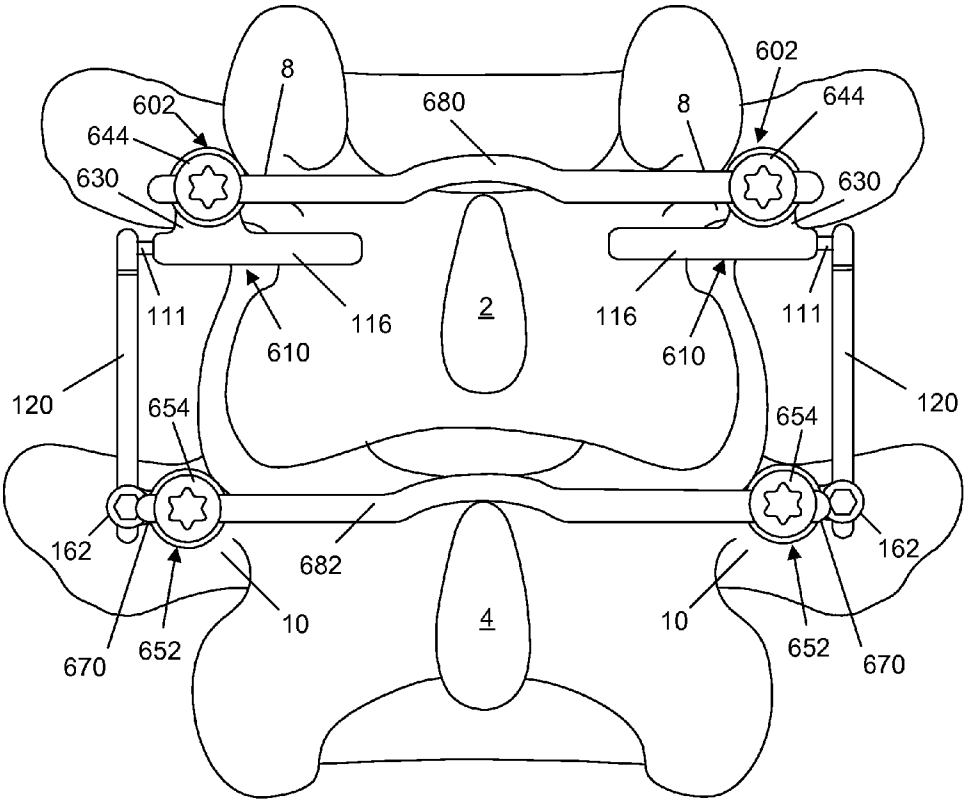
330
116
310
111
120
370
162
152
10
364
370

FIG. 5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602
680
8
602
644
644
630
630
111
610
116
2
116
610
111
120
654
654
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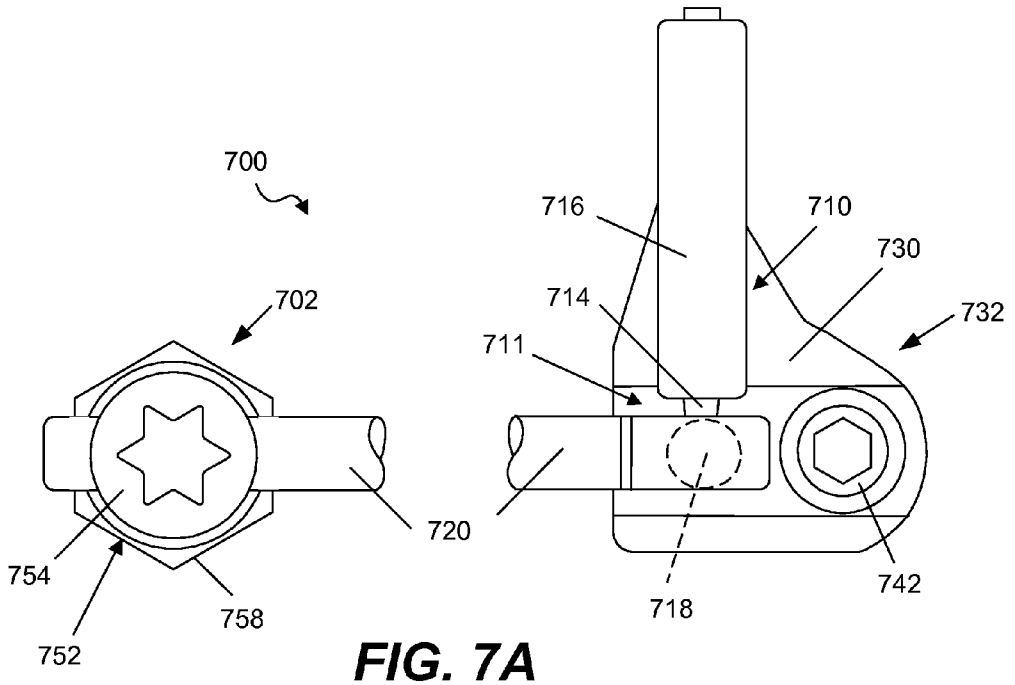
682
162
10
4
10
670
652
652
670

FIG. 6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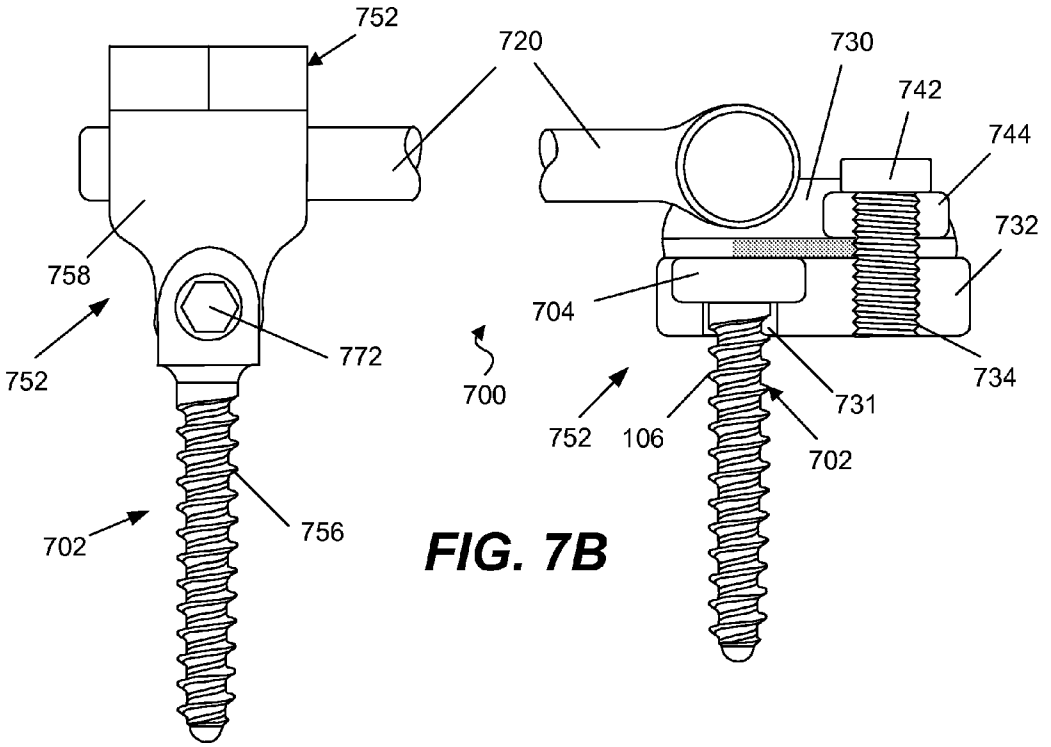
716
710
730
714
732
711
702
720
754
758
752
718
742

FIG. 7A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720
730
742
744
732
758
704
772
752
700
734
731
752
106
702
702
756

FIG. 7B

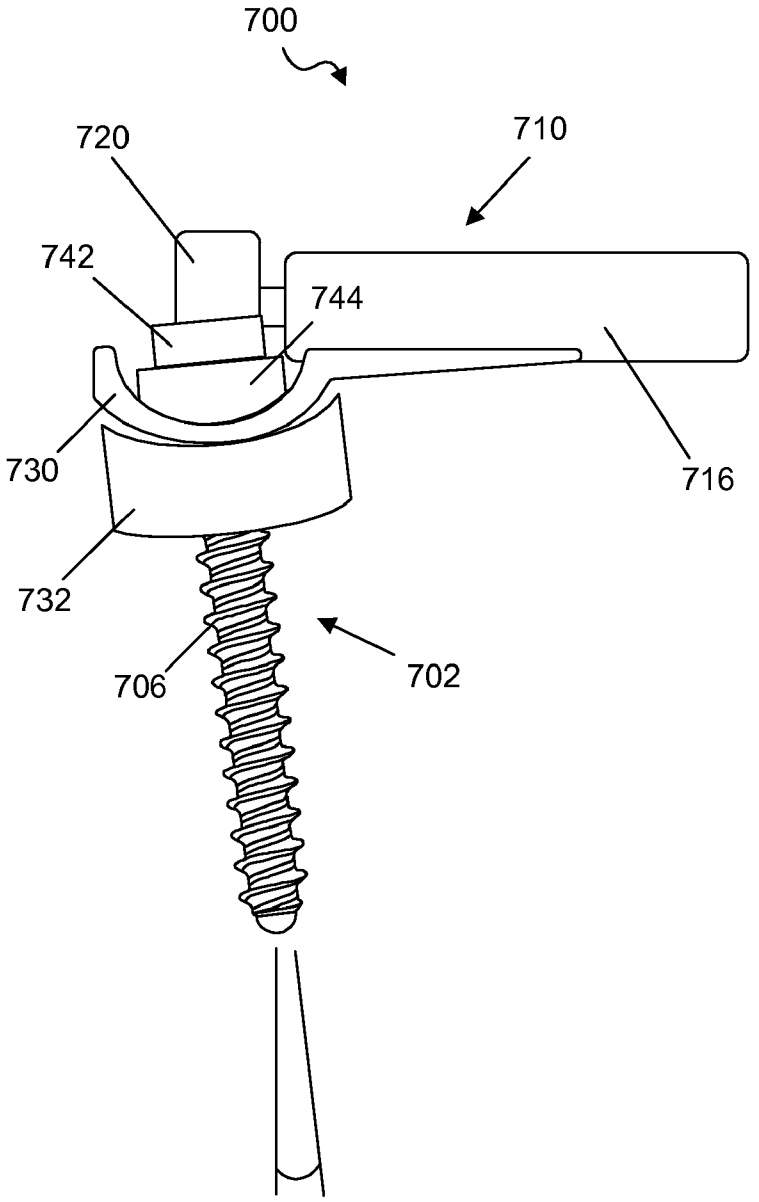



FIG. 7C

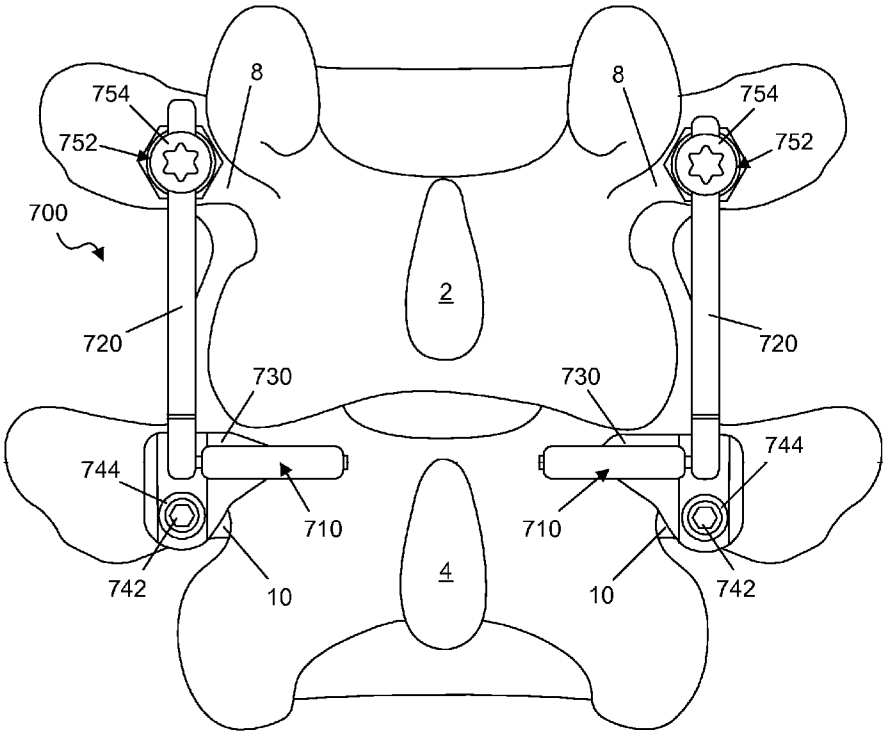

754
752
8
8
754
752
700
2
720
720
730
730
744
744
710
710
742
10
4
10
742

*FIG. 8*

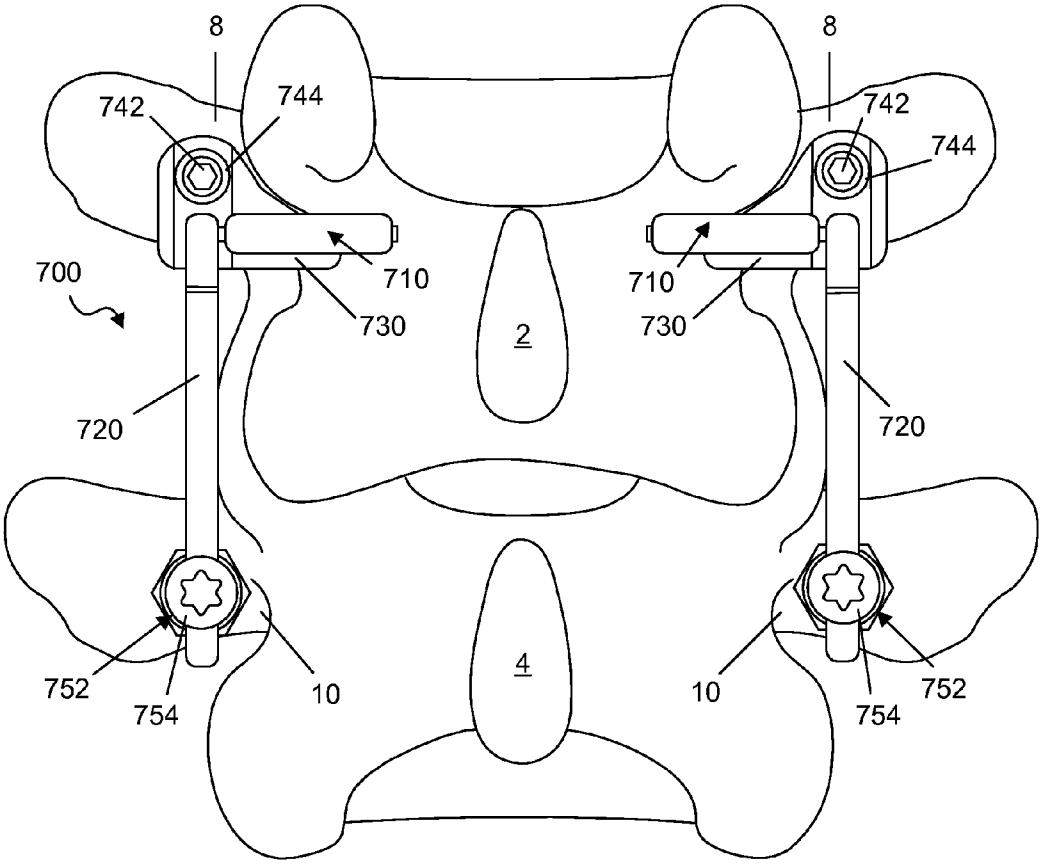
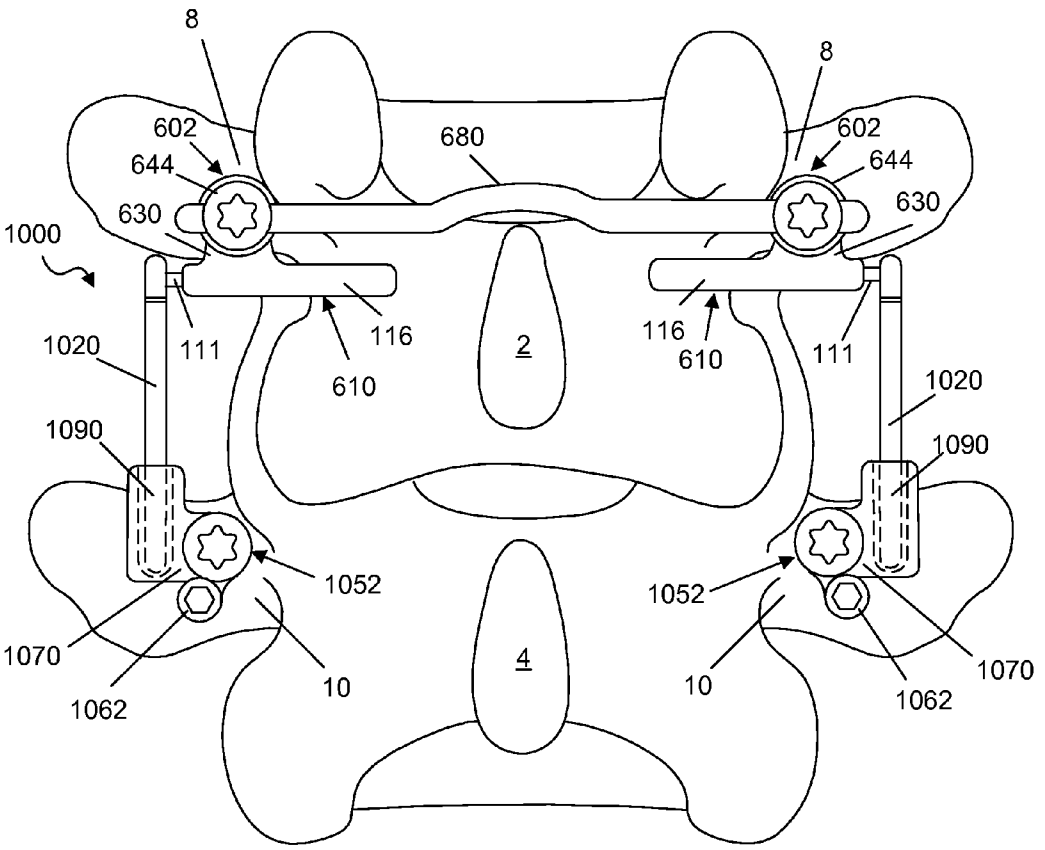

8
8
742
744
742
744
700
710
730
710
730
2
720
720
4
752
754
10
10
754
752

FIG. 9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644
630
1000
680
8
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644
630
1020
111
116
610
2
116
610
111
1020
1090
1090
1052
1052
1070
1062
10
4
10
1070
1062

FIG. 10

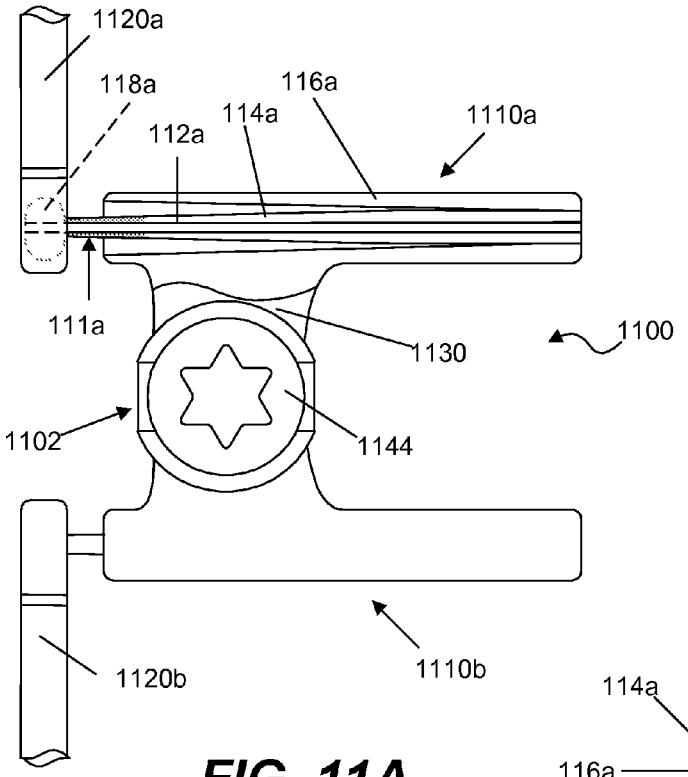



FIG. 11A

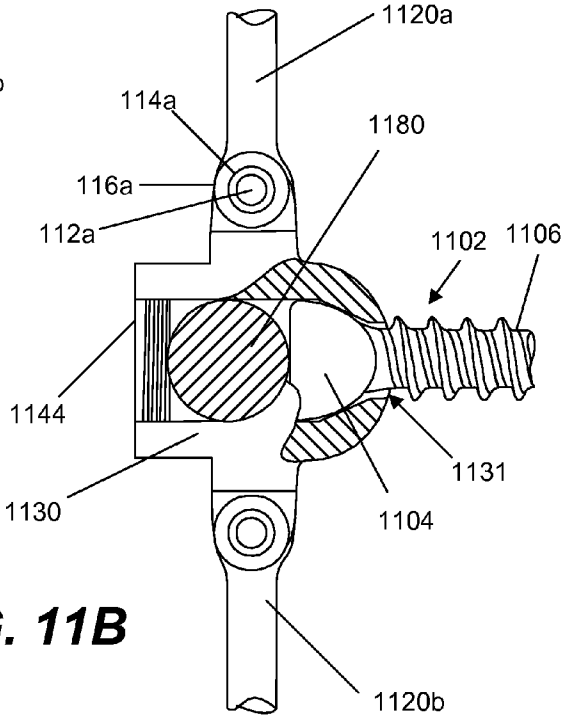



FIG. 11B

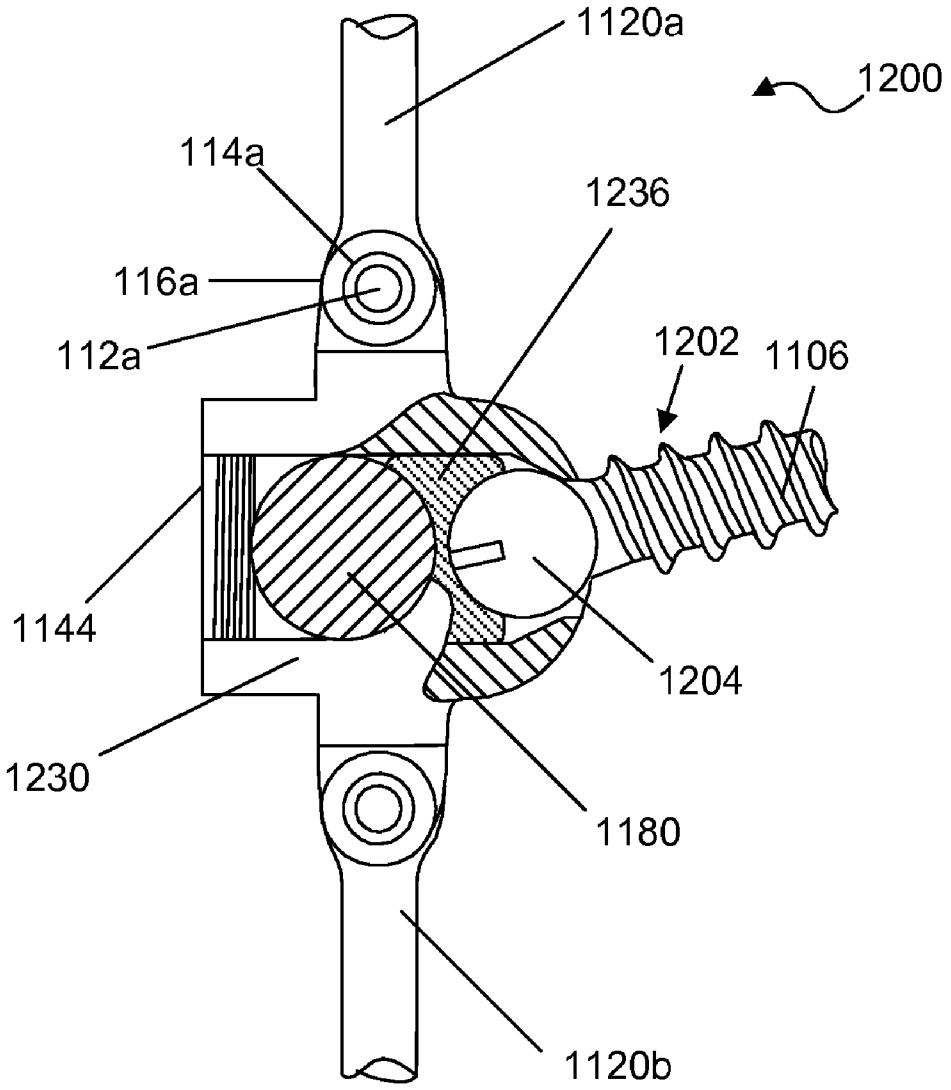

1120a
1200
114a
1236
116a
112a
1202
1106
1144
1204
1230
1180
1120b

FIG. 12

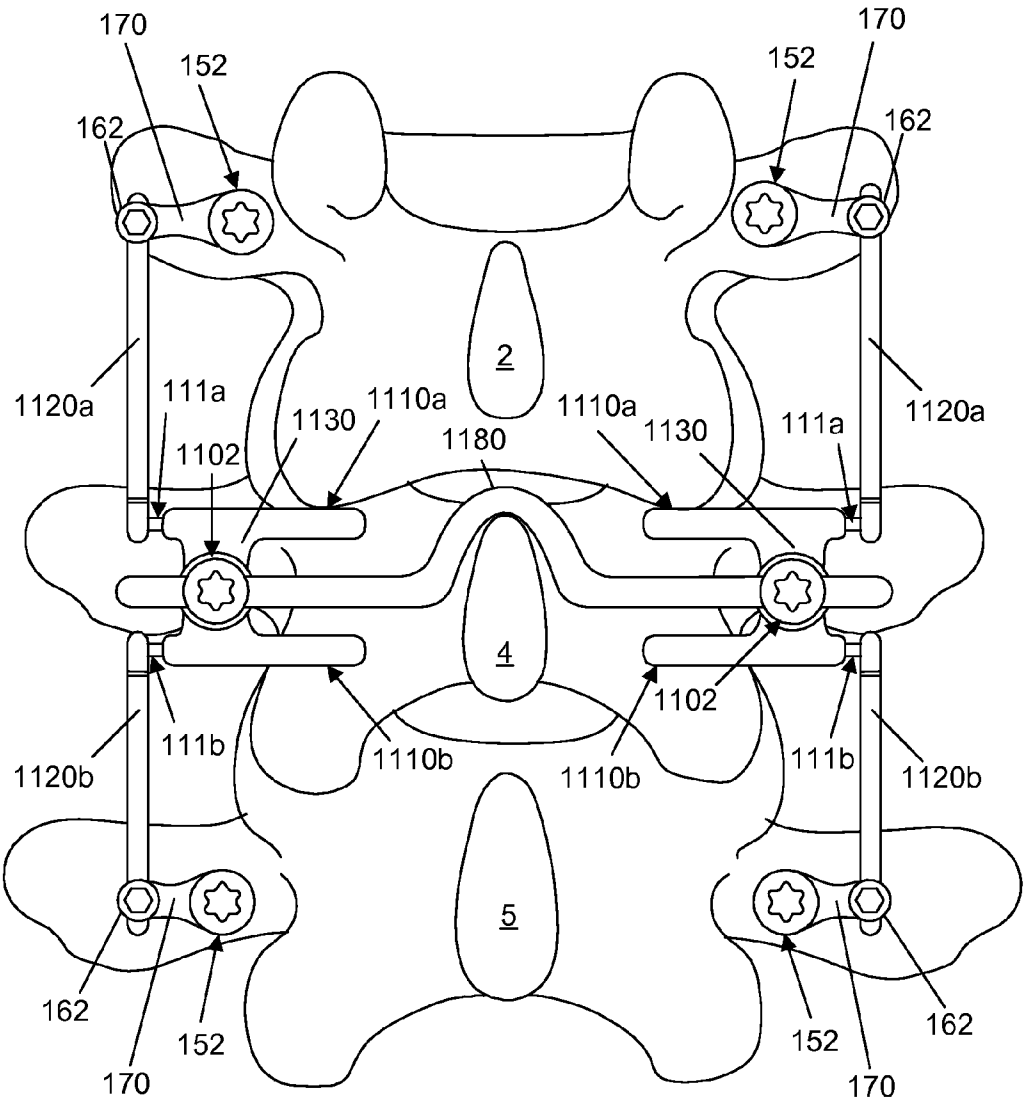

170
152
162
170
152
162
2
1120a
111a
1130
1110a
1102
1180
1110a
1130
111a
1120a
4
1102
1120b
111b
1110b
1110b
111b
1120b
5
162
152
170
152
162
170

FIG. 13

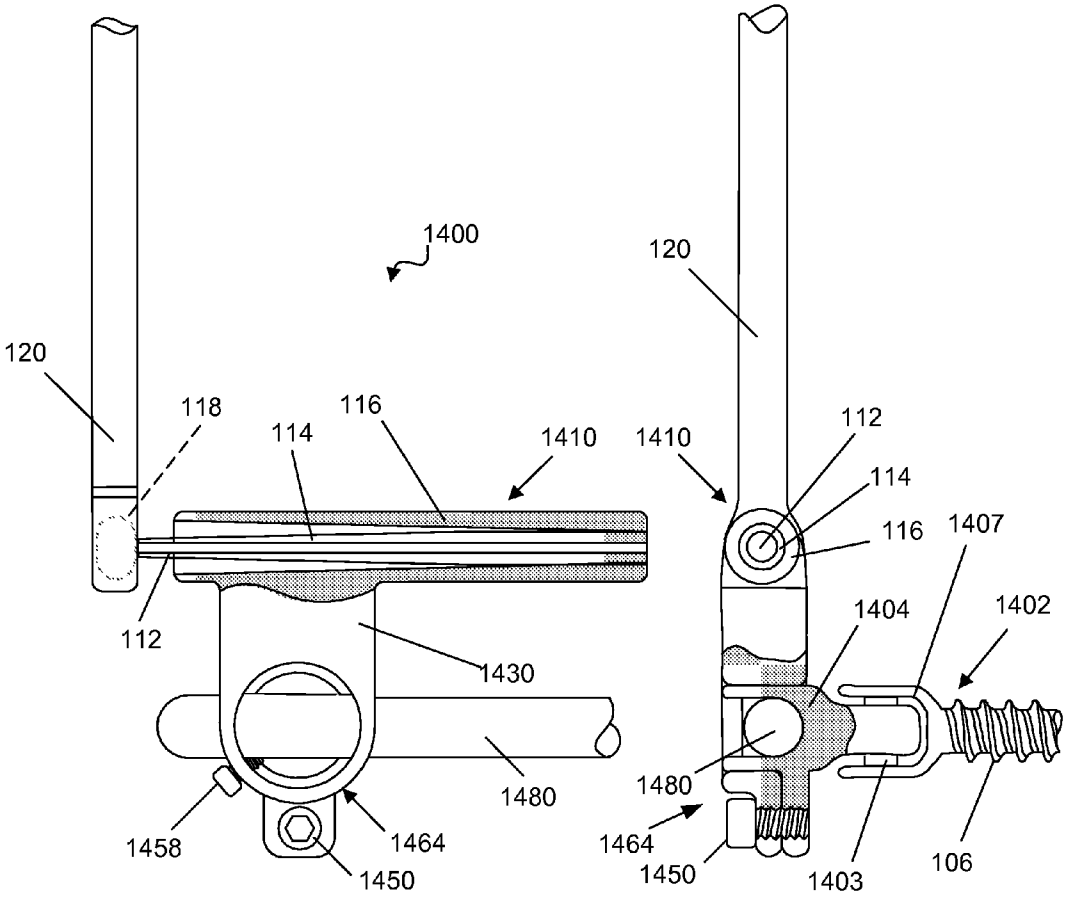



FIG. 14A FIG. 14B

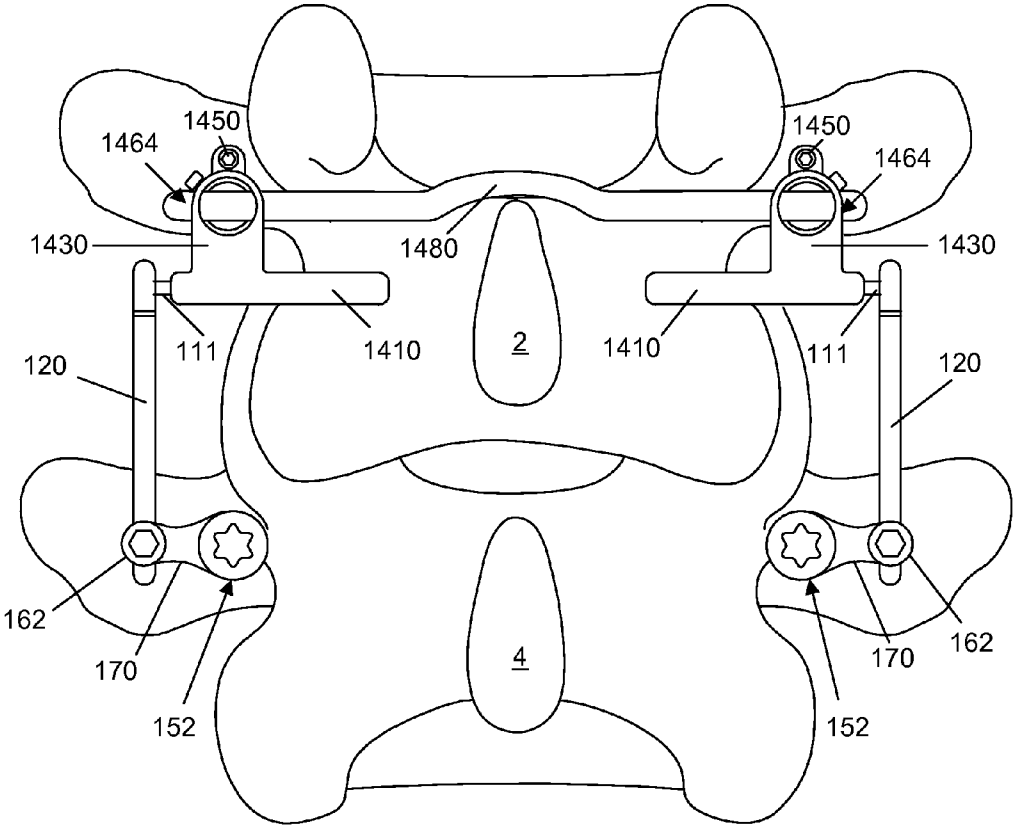

1450
1464
1450
1464
1430
1480
1430
111
1410
2
1410
111
120
120
162
170
152
4
170
162
152

FIG. 15

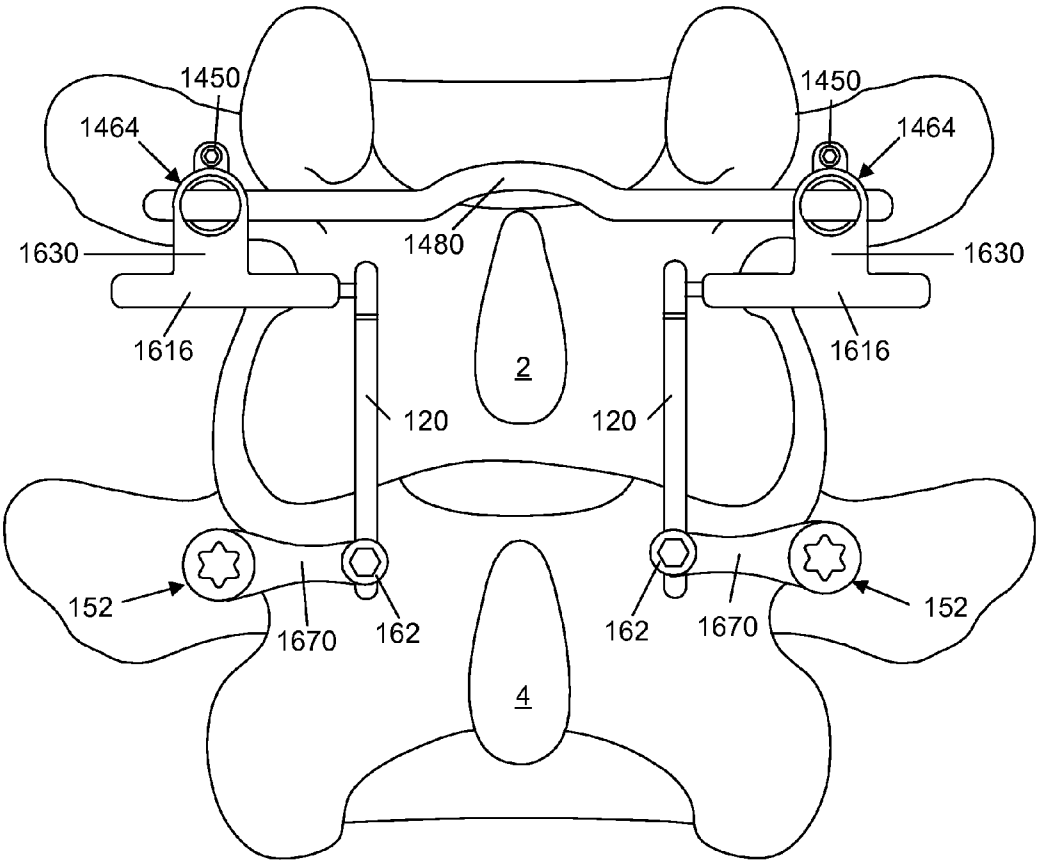

1450
1464
1450
1464
1630
1480
1630
1616
1616
2
120
120
152
1670
162
162
1670
152
4

FIG. 16

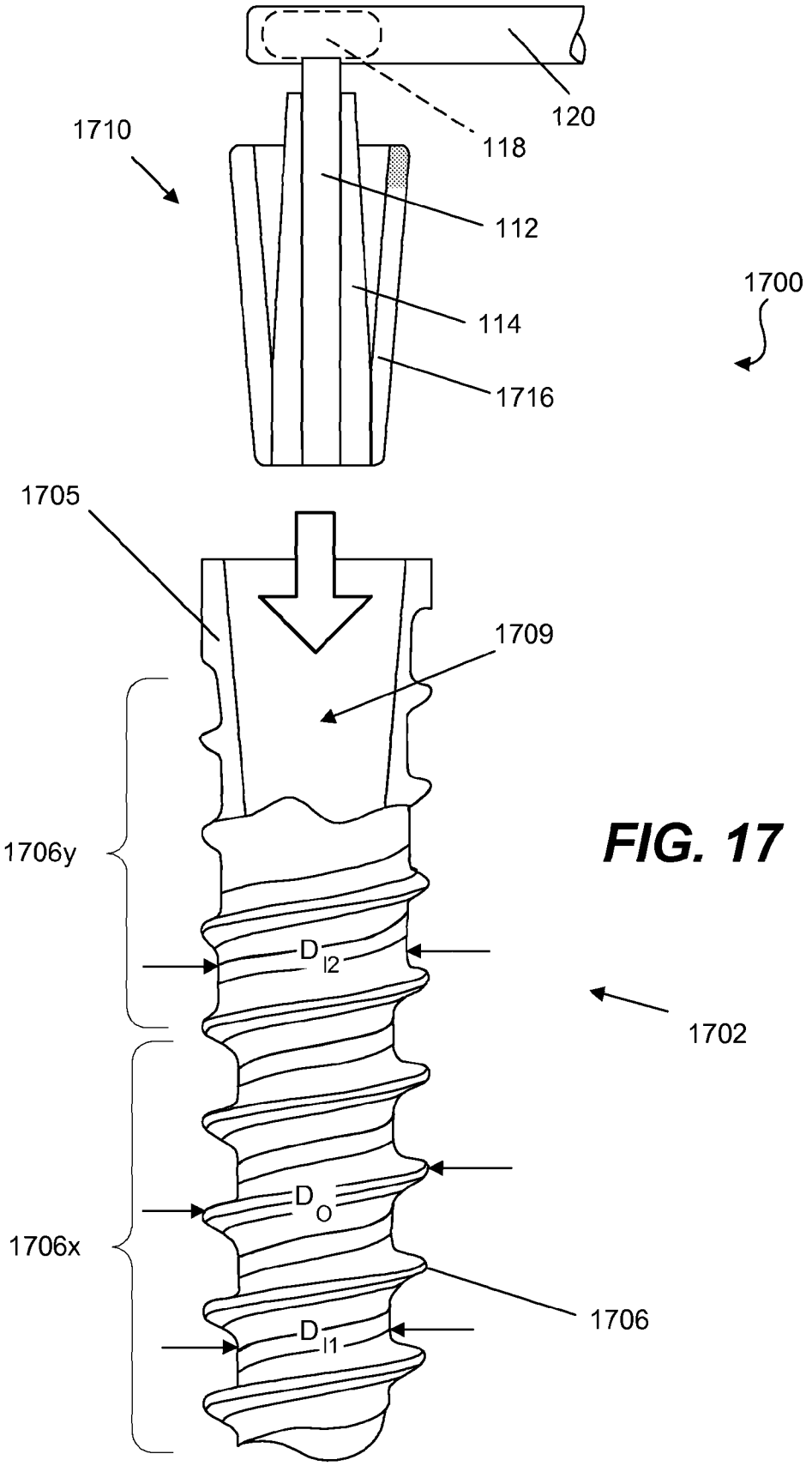

1710
120
118
112
1700
114
1716
1705
1709
1706y
D
I2
1702
1706x
D
O
1706
D
I1

FIG. 17

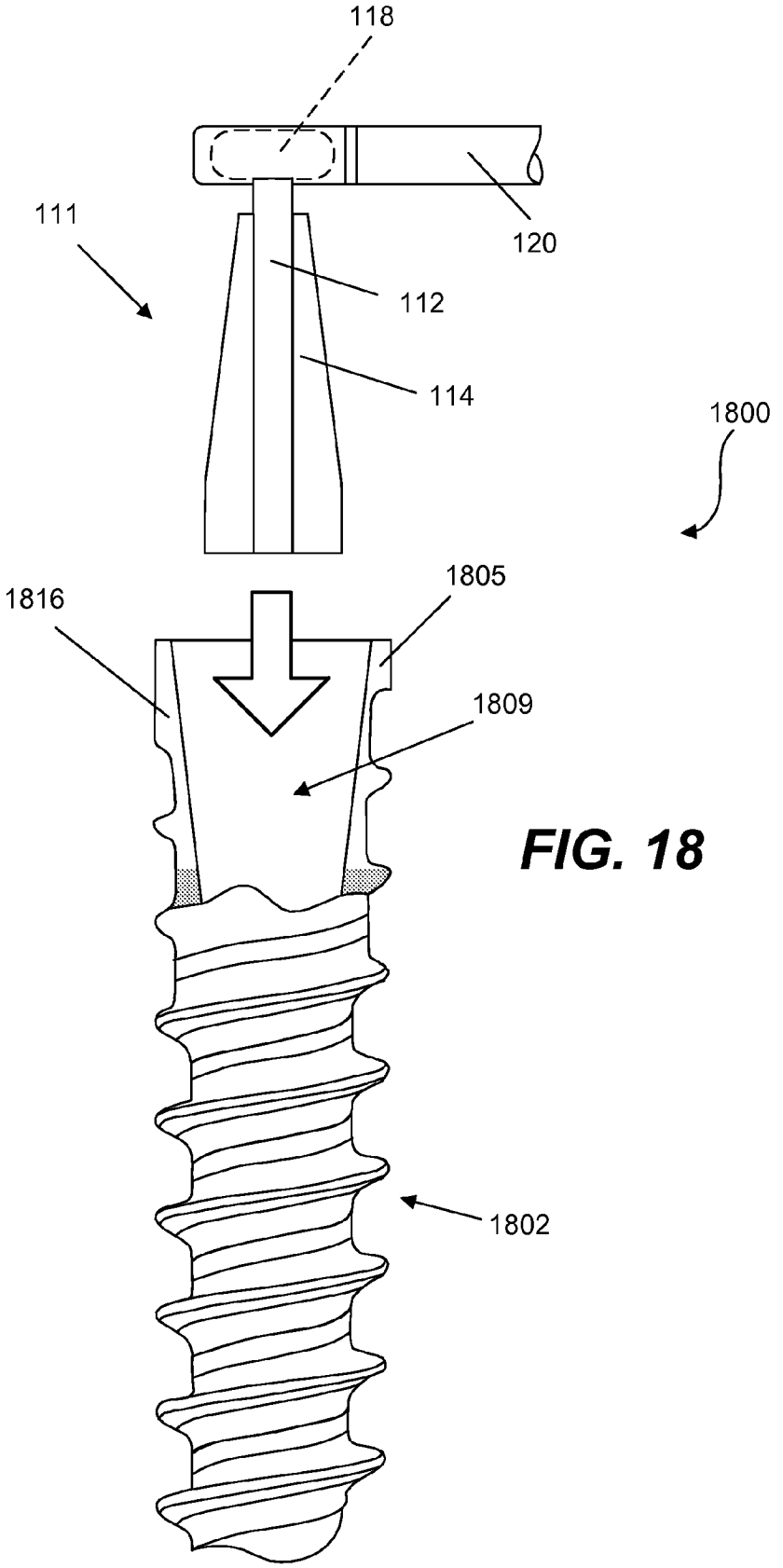



FIG. 18

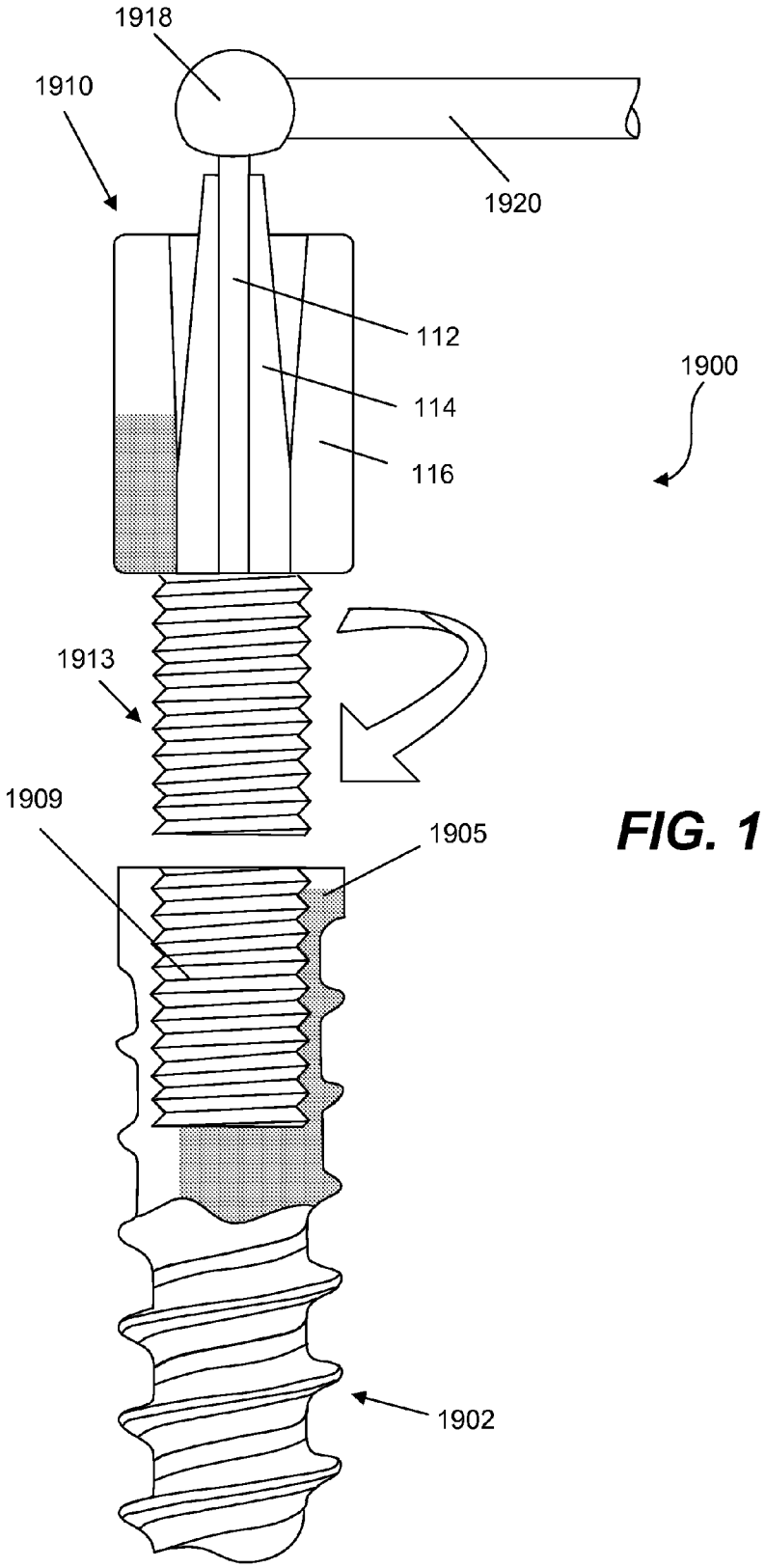



FIG. 19

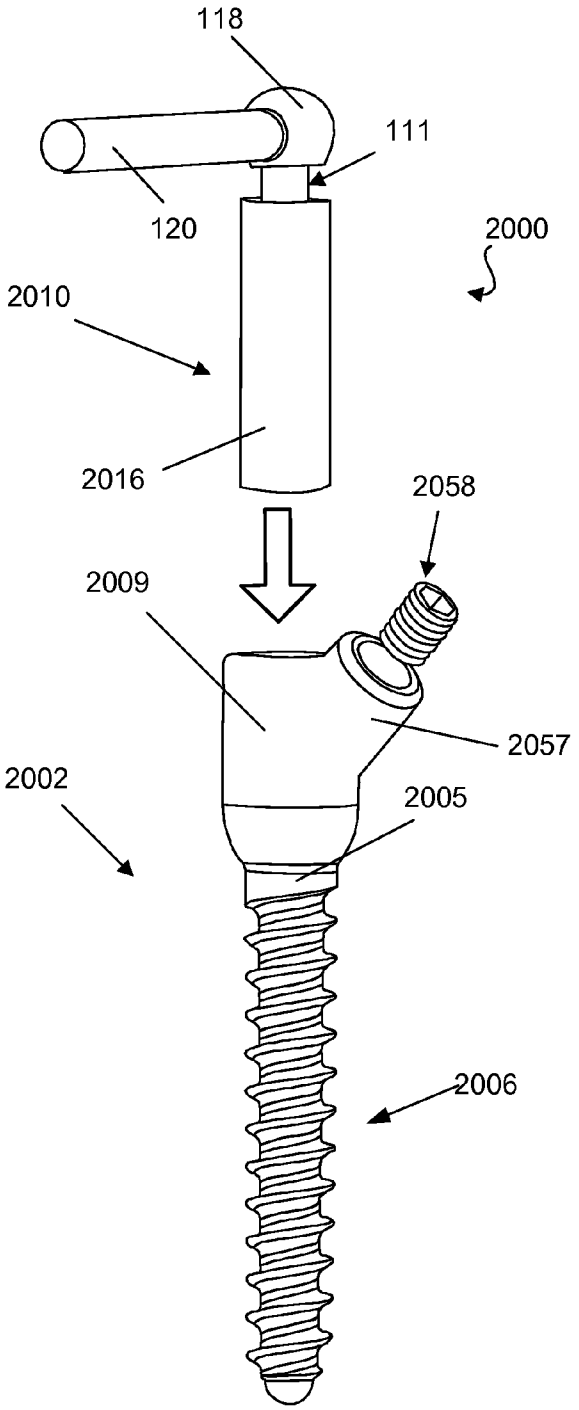



FIG. 20A

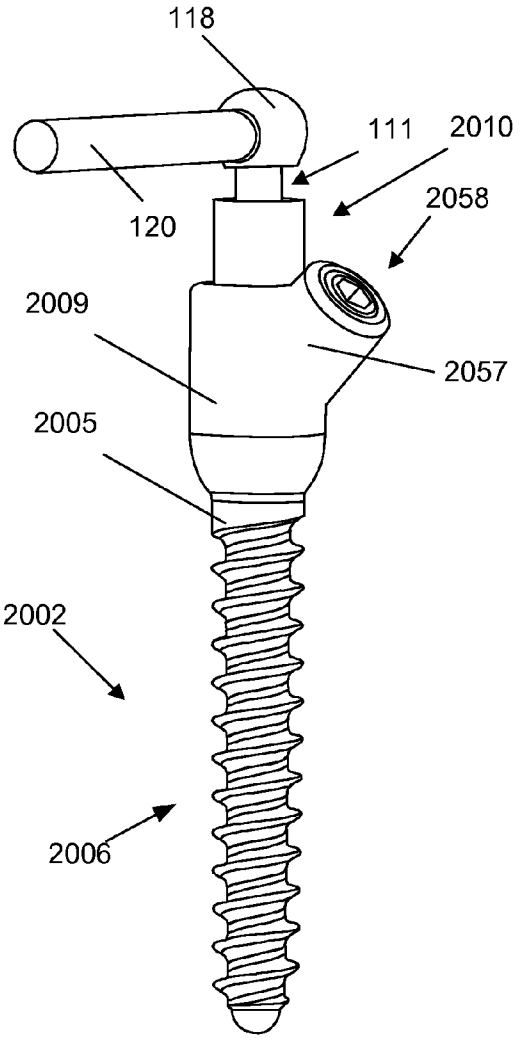
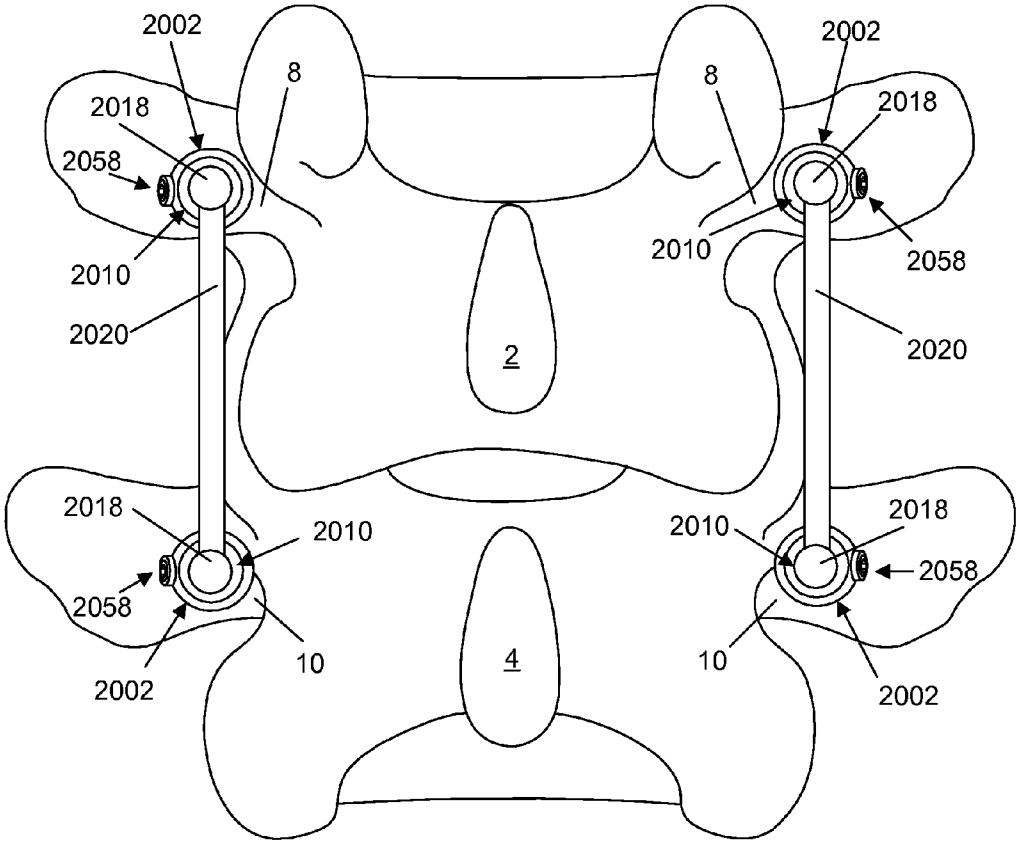



FIG. 20B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8
2018
2058
2010
2020
2
2018
2010
2058
10
2002
4
2002
8
2018
2010
2058
2020
2010
2018
2058
10
2002

FIG. 21

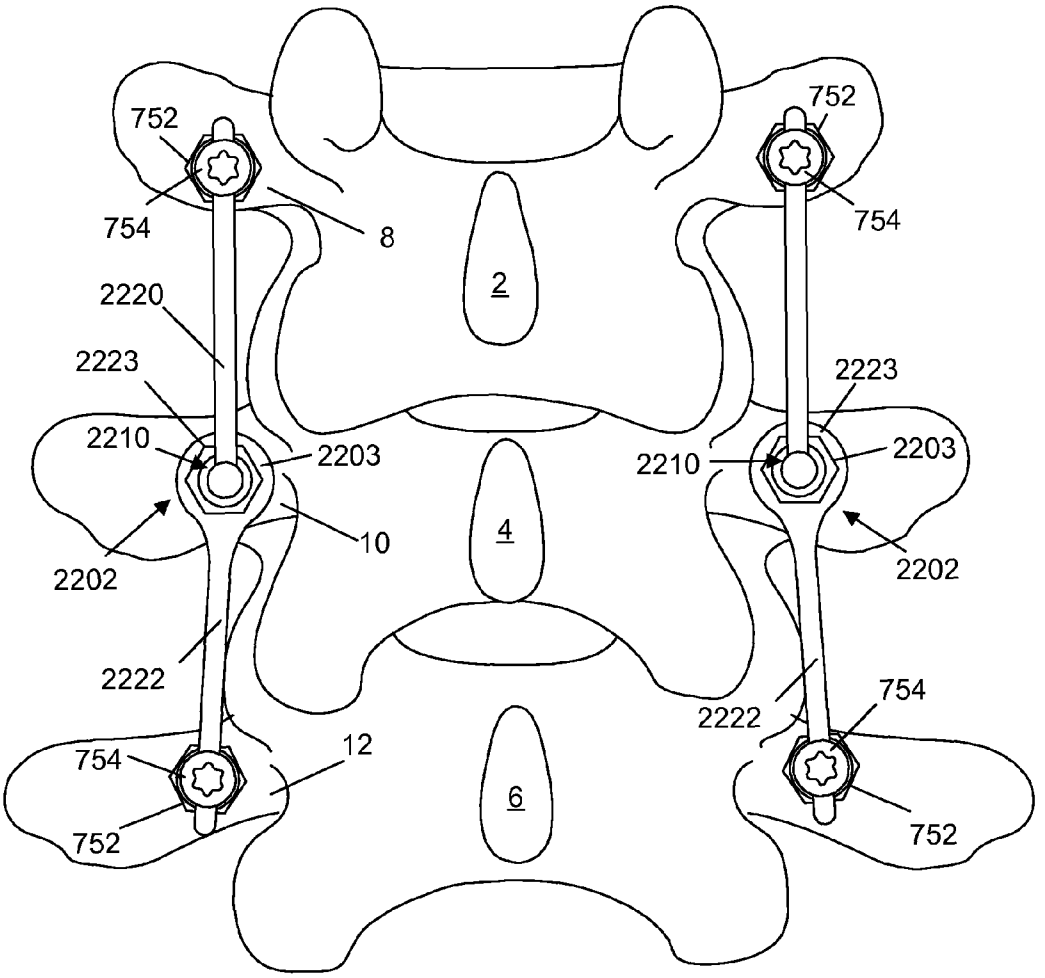
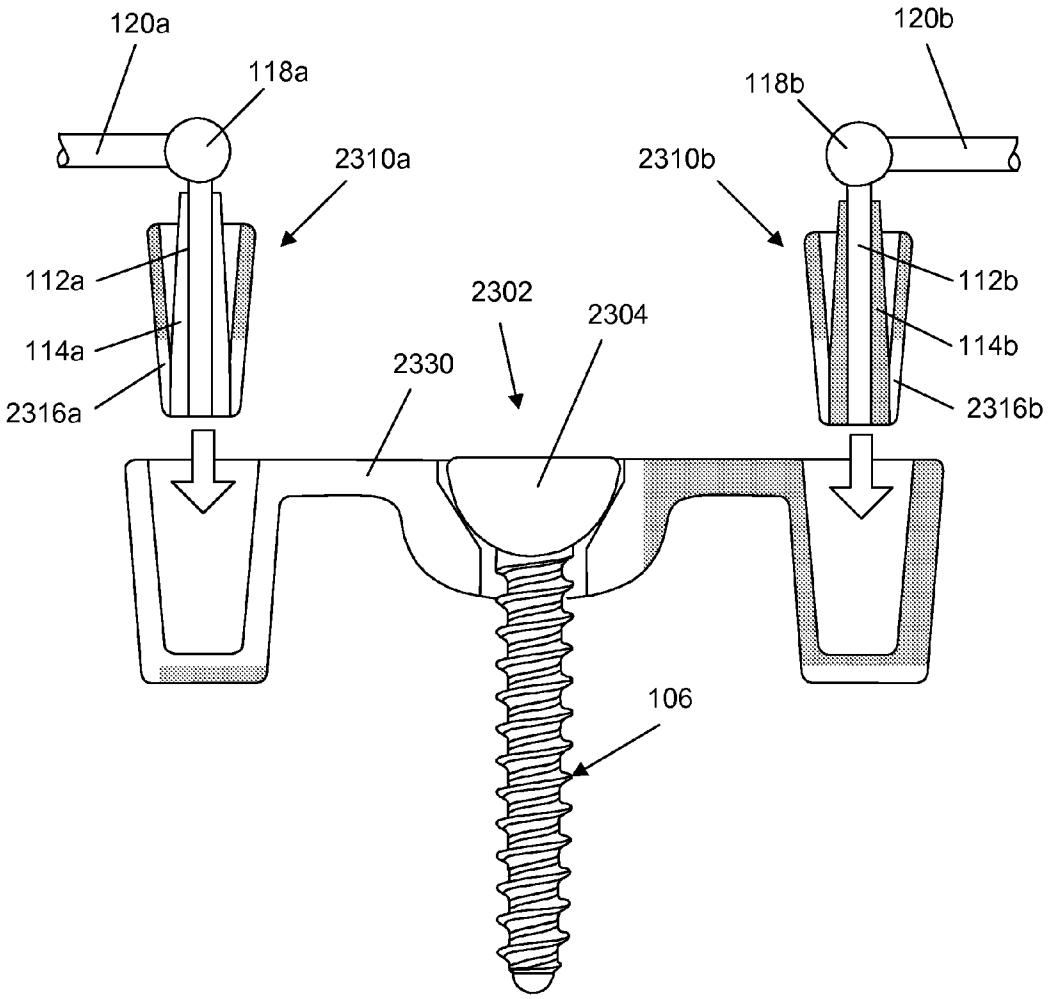

752
754
8
2
752
754
2220
2223
2210
2203
2223
2210
2203
10
4
2202
2202
2222
2222
754
754
12
6
752
752

FIG. 22


120a
118a
2310a
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2330
120b
118b
2310b
112b
114b
2316b
106

FIG. 23

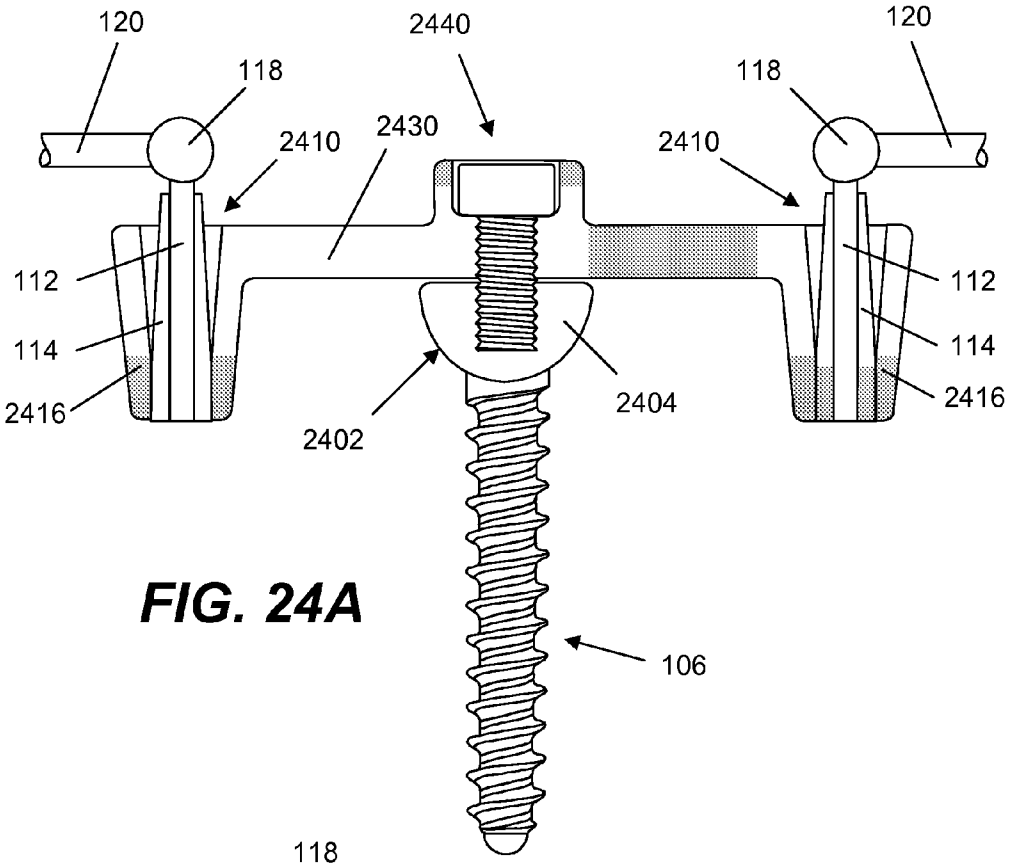


FIG. 24A

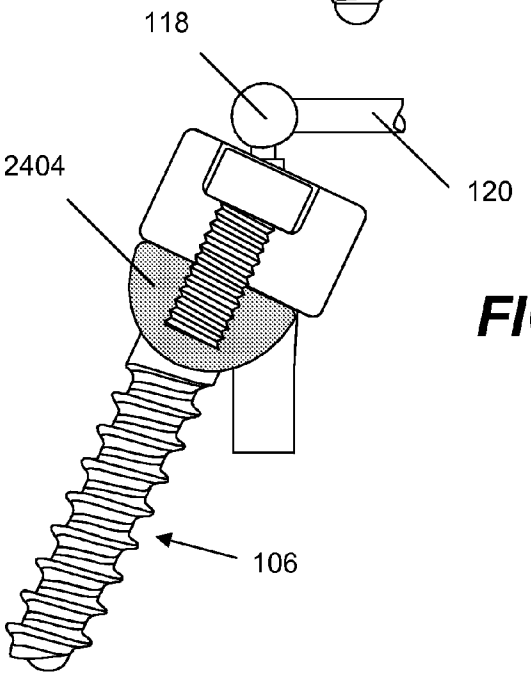


FIG. 24B

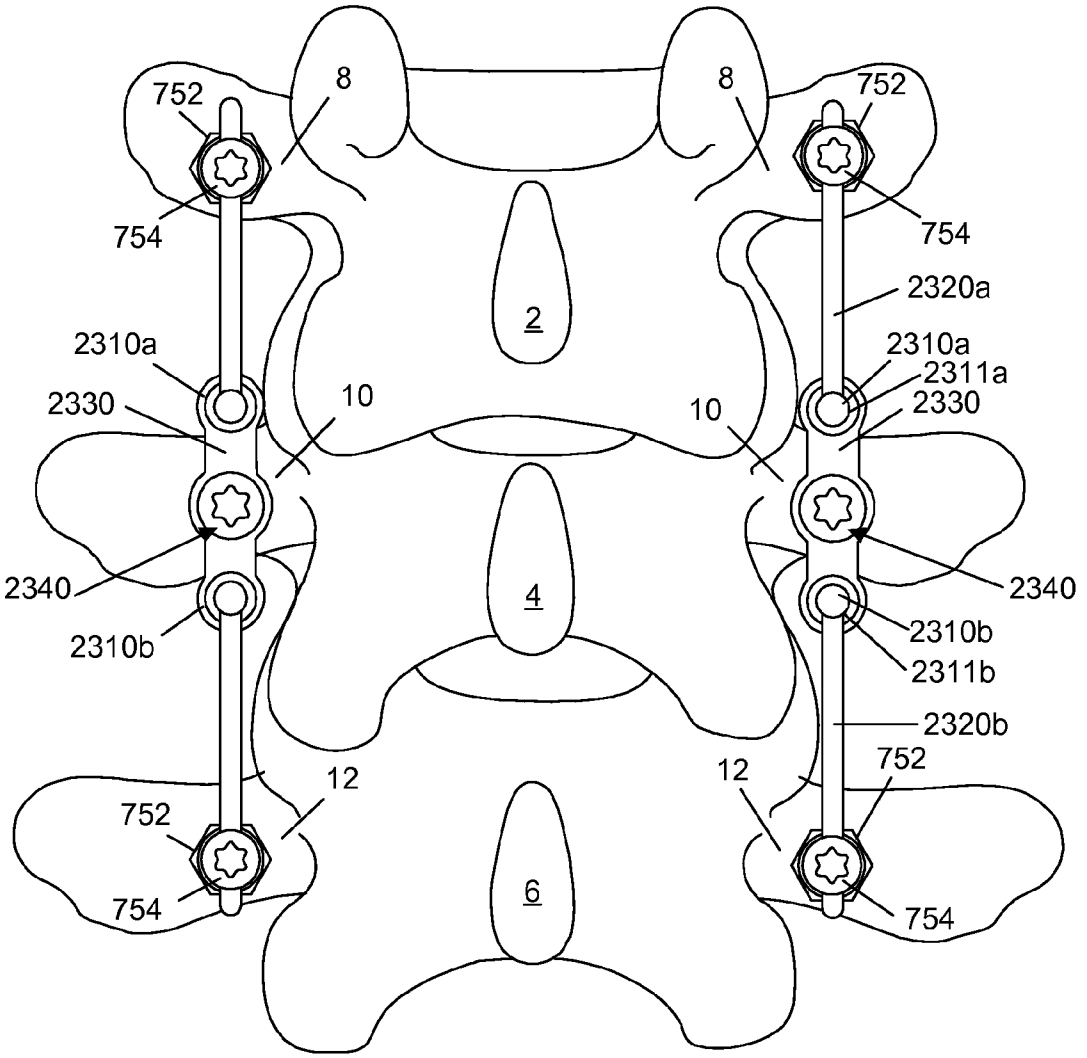
752
8
8
752
754
754
2320a
2
2310a
2310a
2311a
2330
10
10
2330
2340
2340
4
2310b
2310b
2311b
2320b
12
12
752
752
754
754
6

FIG. 25

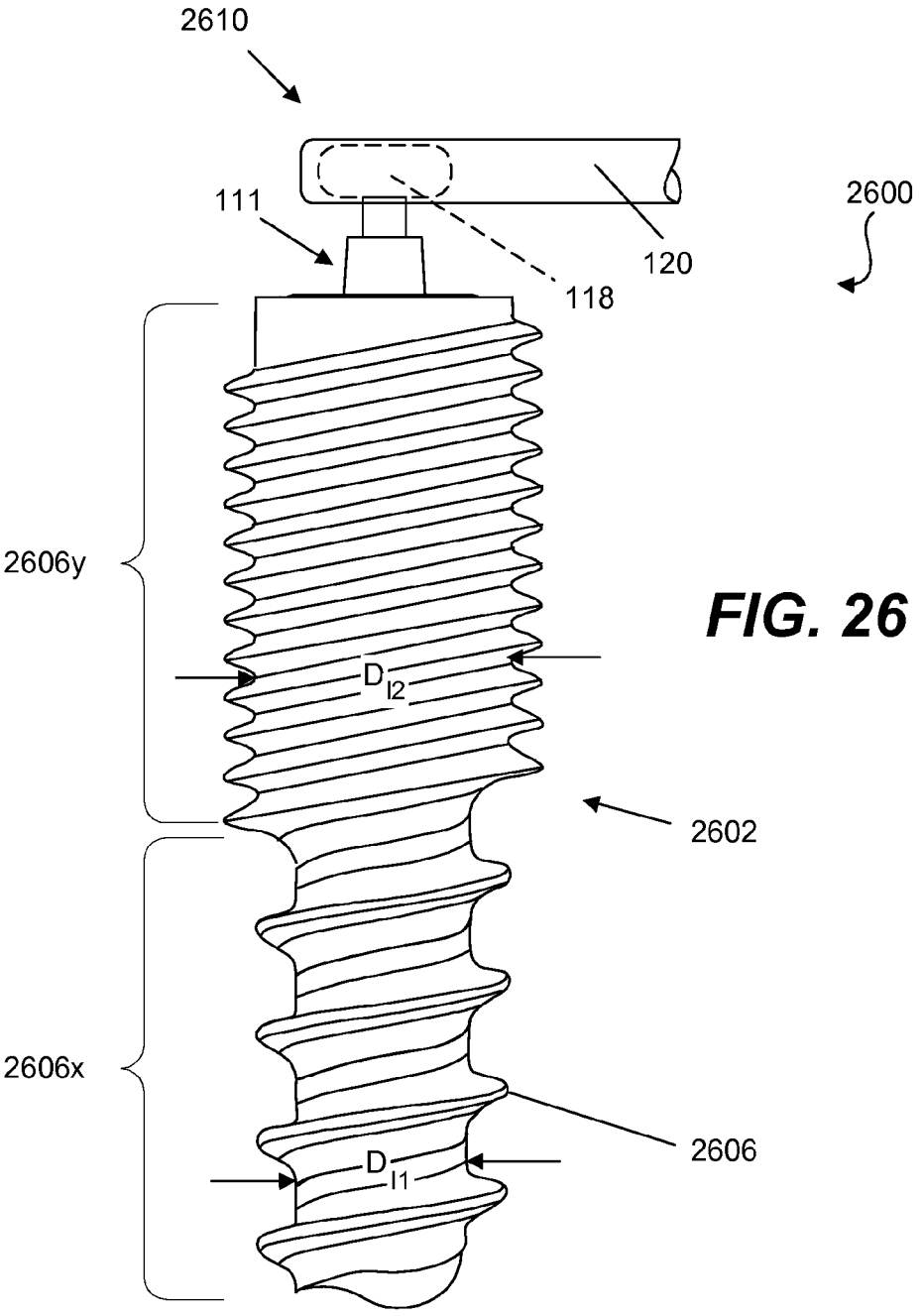


FIG. 26

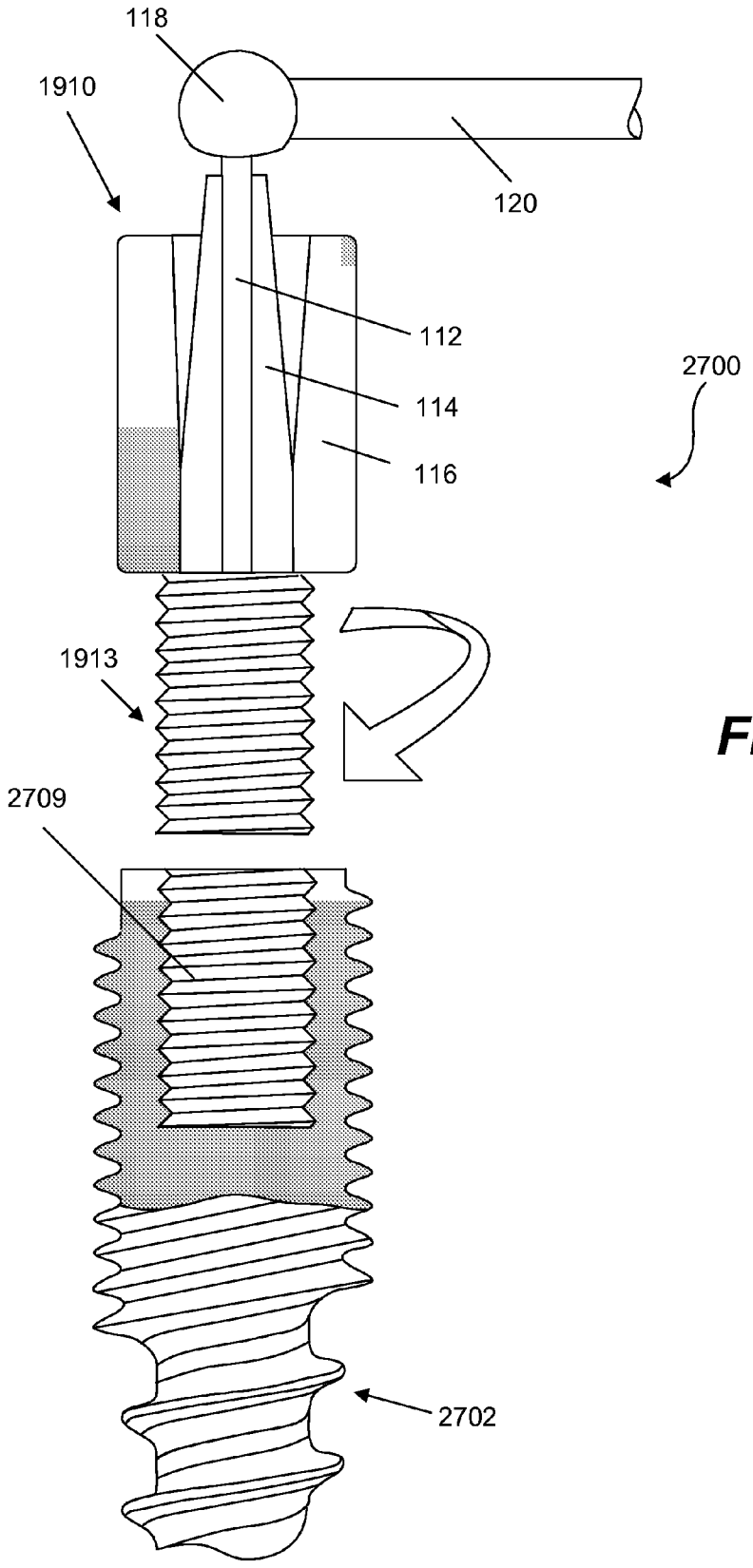


FIG. 27

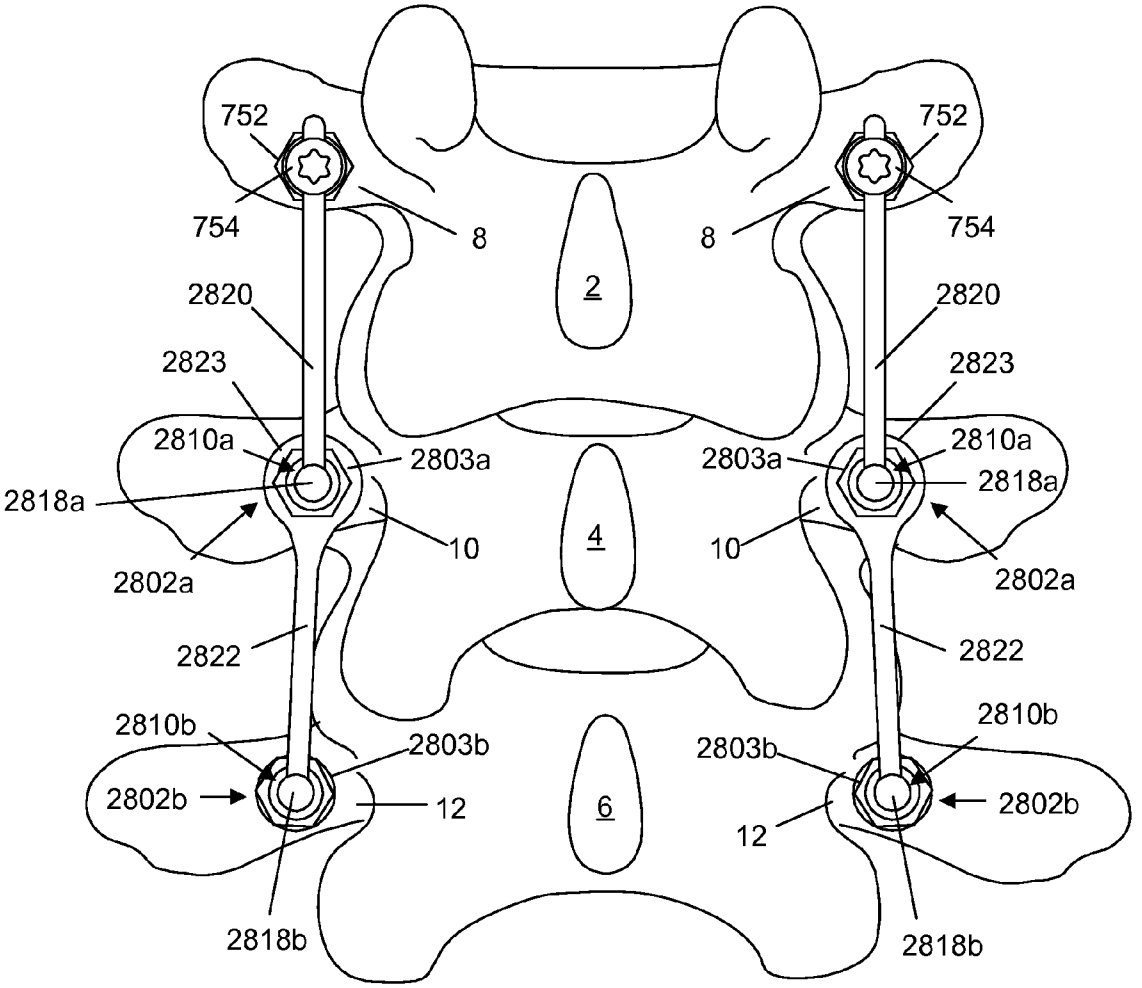
752
754
8
2820
2823
2810a
2803a
2818a
2802a
10
2822
2810b
2803b
2802b
12
2818b
2
4
6
752
754
8
2820
2823
2810a
2803a
2818a
2802a
10
2822
2810b
2803b
2802b
12
2818b

FIG. 28

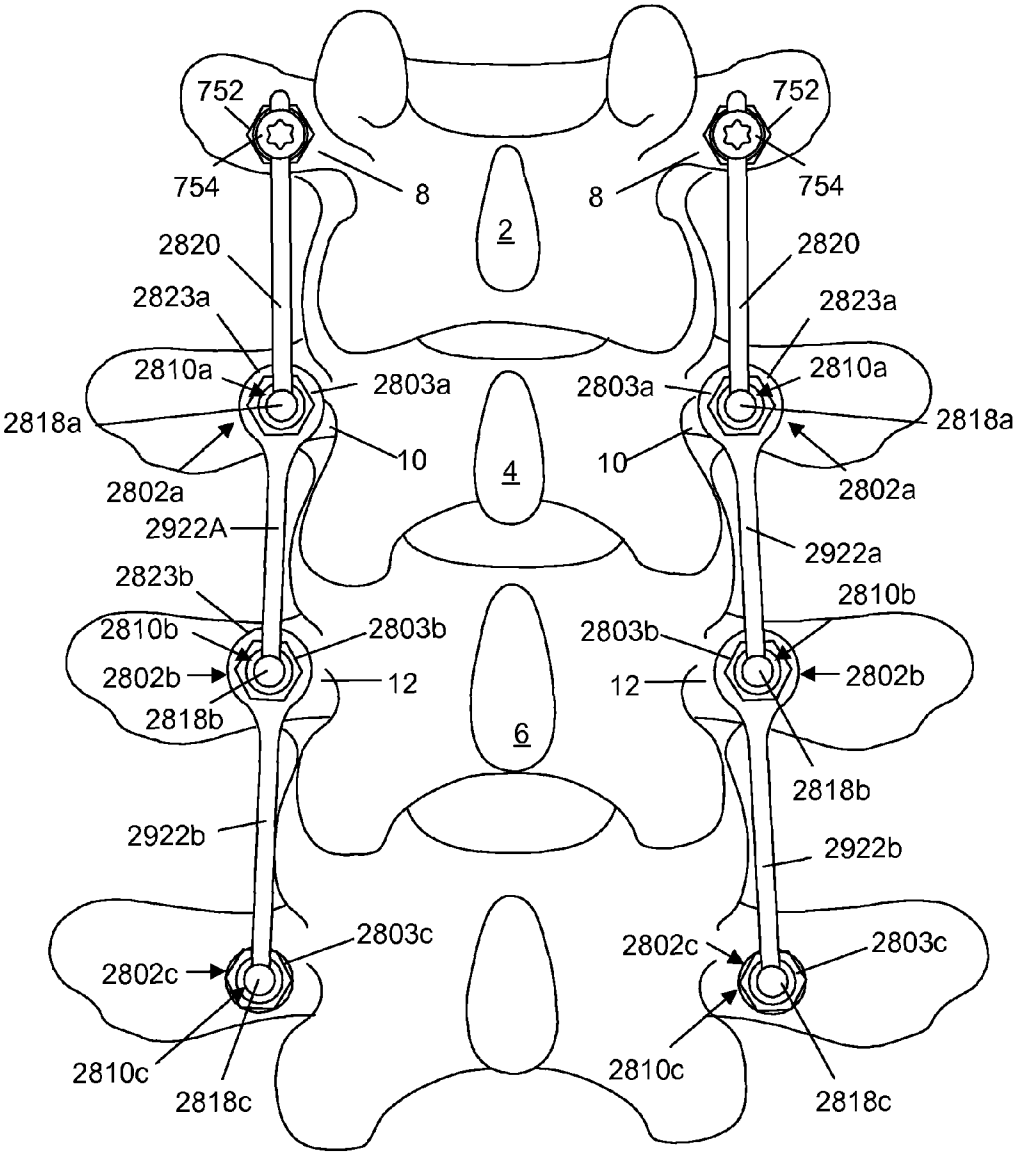
752
754
8
2820
2823a
2810a
2803a
2818a
10
2802a
2922A
2823b
2810b
2803b
2802b
12
2818b
2922b
2803c
2802c
2810c
2818c
2
4
6
752
754
8
2820
2823a
2810a
2803a
2818a
10
2802a
2922a
2810b
2803b
2802b
12
2818b
2922b
2803c
2802c
2810c
2818c

*FIG. 29*

# SPINE IMPLANT WITH A DEFELCTION ROD SYSTEM ANCHORED TO A BONE ANCHOR AND METHOD

## CLAIM TO PRIORITY

This application claims priority to all of the following applications including U.S. Provisional Application No. 60/942,162, filed Jun. 5, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,260, filed Aug. 1, 2007, entitled "Shaped Horizontal Rod for Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,273, filed Aug. 1, 2007, entitled "Multi-directional Deflection Profile for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,305, filed Aug. 1, 2007, entitled "A Horizontal Rod with a Mounting Platform for a Dynamic Stabilization and Motion Preservation Spinal Implant System and Method",

U.S. patent application Ser. No. 11/832,330, filed Aug. 1, 2007, entitled "Multi-dimensional Horizontal Rod for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,338, filed Aug. 1, 2007, entitled "A Bone Anchor With a Yoke-Shaped anchor head for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,358, filed Aug. 1, 2007, entitled "A Bone Anchor With a Curved Mounting Element for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,377, filed Aug. 1, 2007, entitled "Reinforced Bone Anchor for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,400, filed Aug. 1, 2007, entitled "A Bone Anchor With a Compressor Element for Receiving a Rod for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,413, filed Aug. 1, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method with a Deflection Rod",

U.S. patent application Ser. No. 11/832,426, filed Aug. 1, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method with a Deflection Rod Mounted in Close Proximity to a Mounting Rod",

U.S. patent application Ser. No. 11/832,436, filed Aug. 1, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,446, filed Aug. 1, 2007, entitled "Super-Elastic Deflection Rod for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,470, filed Aug. 1, 2007, entitled "Revision System and Method for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,485, filed Aug. 1, 2007, entitled "Revision System for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",



U.S. patent application Ser. No. 11/832,494, filed Aug. 1, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,517, filed Aug. 1, 2007, entitled "Implantation Method for Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,527, filed Aug. 1, 2007, entitled "Modular Spine Treatment Kit for Dynamic Stabilization and Motion Preservation of the Spine",

U.S. patent application Ser. No. 11/832,534, filed Aug. 1, 2007, entitled "Horizontally Loaded Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. patent application Ser. No. 11/832,548, filed Aug. 1, 2007, entitled "Dynamic Stabilization and Motion Preservation Spinal Implantation System with Horizontal Deflection Rod and Articulating Vertical Rods",

U.S. patent application Ser. No. 11/832,557, filed Aug. 1, 2007, entitled "An Anchor System for a Spine Implantation System That Can Move About three Axes",

U.S. patent application Ser. No. 11/832,562, filed Aug. 1, 2007, entitled "Rod Capture Mechanism for Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. Provisional Application No. 61/028,792, filed Feb. 14, 2008, entitled "A Deflection Rod System for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method",

U.S. Provisional Application 61/031,598, filed Feb. 26, 2008, entitled "A Deflection Rod System for a Dynamic Stabilization and Motion Preservation Spinal Implantation System and Method", and

U.S. Provisional Application No. 61/057,340, filed May 30, 2008, entitled "A Spine Implant With A Deflection Rod System Aligned With A Bone Anchor And Method".

All of the afore-mentioned applications are incorporated herein by reference in their entireties.

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is related to all of the following applications including U.S. patent application Ser. No. 12/130,335, filed May 30, 2008, "A Deflection Rod System For A Spine Implant Including An Inner Rod And An Outer Shell And Method";

U.S. patent application Ser. No. 12/130,359, filed May 30, 2008, entitled "A Deflection Rod System With A Deflection Contouring Shield For A Spine Implant And Method";

U.S. patent application Ser. No. 12/130,367, filed May 30, 2008, entitled "Dynamic Stabilization And Motion Preservation Spinal Implantation System With A Shielded Deflection Rod System And Method";

U.S. patent application Ser. No. 12/130,377, filed May 30, 2008, entitled "A Deflection Rod System For Spine Implant With End Connectors And Method";

U.S. patent application Ser. No. 12/130,383, filed May 30, 2008, entitled "A Deflection Rod System For A Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,395, filed May 30, 2008, entitled "A Deflection Rod System For A Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,411, filed May 30, 2008, entitled "A Deflection Rod System With Mount For

Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,423, filed May 30, 2008, entitled "A Deflection Rod System With A Non-Linear Deflection To Load Characteristic For Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,454, filed May 30, 2008, entitled "A Deflection Rod System Dimensioned For Deflection To A Load Characteristic For Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,457, filed May 30, 2008, entitled "A Deflection Rod System For Use With A Vertebral Fusion Implant For Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,467, filed May 30, 2008, entitled "A Dual Deflection Rod System For Dynamic Stabilization And Motion Preservation Spinal Implantation System And Method";

U.S. patent application Ser. No. 12/130,475, filed May 30, 2008, entitled "Method For Implanting A Deflection Rod System And Customizing The Deflection Rod System For A Particular Patient Need For Dynamic Stabilization And Motion Preservation Spinal Implantation System";

U.S. patent application Ser. No. 12/130,095, filed May 30, 2008, entitled "A Spine Implant With A Deflection Rod System Including A Deflection Limiting Shield Associated With A Bone Screw And Method";

U.S. patent application Ser. No. 12/130,127, filed May 30, 2008, entitled "A Spine Implant With A Dual Deflection Rod System Including A Deflection Limiting Shield Associated With A Bone Screw And Method"; and

U.S. patent application Ser. No. 12/130,152, filed May 30, 2008, entitled "A Spine Implant With A Deflection Rod System And Connecting Linkages And Method"

All of the afore-mentioned applications are incorporated herein by reference in their entireties.

## BACKGROUND OF INVENTION

The most dynamic segment of orthopedic and neurosurgical medical practice over the past decade has been spinal devices designed to fuse the spine to treat a broad range of degenerative spinal disorders. Back pain is a significant clinical problem and the annual costs to treat it, both surgical and medical, is estimated to be over $2 billion. Motion preserving devices to treat back and extremity pain have, however, created a treatment alternative to or in combination with fusion for degenerative disk disease.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a posterior view of an embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **1**B is a lateral view of the dynamic spine stabilization system of FIG. **1**A.

FIG. **2** is a posterior view of the dynamic spine stabilization system of FIG. **1**A implanted and extending between two vertebrae of a spine.

FIG. **3**A is a posterior view of the dynamic spine stabilization system of FIG. **1**A implanted as shown in FIG. **2** and further comprising locking screws to resist rotation of the dynamic spine stabilization system.

FIG. **3**B is a posterior view of another embodiment of the dynamic spine stabilization system of the invention.

FIG. **4** is a posterior view of another embodiment of the dynamic spine stabilization system of the invention.

FIG. **5** is a posterior view of another embodiment of the dynamic spine stabilization system of the invention.

FIG. **6** is a posterior view of yet another embodiment of the dynamic spine stabilization system of the invention including horizontal rods to resist rotation.

FIG. **7**A is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **7**B is a lateral view of the dynamic spine stabilization system of FIG. **7**A.

FIG. **7**C is a caudal view of the dynamic spine stabilization system of FIG. **7**A.

FIG. **8** is a posterior view of the dynamic spine stabilization system of FIG. **7**A implanted and extending between two vertebrae of a spine.

FIG. **9** is a posterior view of the dynamic spine stabilization system of FIG. **7**A implanted in an alternative arrangement to FIG. **8** and extending between the two vertebrae.

FIG. **10** is a posterior view of yet another embodiment of a dynamic spine stabilization system in accordance with the present invention implanted and extending between two vertebrae of a spine.

FIG. **11**A is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **11**B is a lateral view of the dynamic spine stabilization system of FIG. **11**A.

FIG. **12** is a lateral view of the dynamic spine stabilization system of FIG. **11**A comprising an alternative seating arrangement for a horizontal rod.

FIG. **13** is a posterior view of the dynamic spine stabilization system of FIG. **11**A implanted and extending between a vertebra of the spine and two adjacent vertebrae.

FIG. **14**A is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **14**B is a lateral view of the dynamic spine stabilization system of FIG. **14**A.

FIG. **15** is a posterior view of the dynamic spine stabilization system of FIG. **14**A implanted and extending between two vertebrae of a spine.

FIG. **16** is a posterior view of yet another embodiment of a dynamic spine stabilization system in accordance with the present invention implanted and extending between two vertebrae of a spine.

FIG. **17** is a lateral view of a further embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **18** is a lateral view of yet another embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **19** is a lateral view of a further embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **20**A is an exploded perspective view of yet another embodiment of a dynamic spine system in accordance with the present invention.

FIG. **20**B is an perspective view the dynamic spin stabilization system of FIG. **20**A with the distraction rod system and set screw seated within the anchoring device.

FIG. **21** is a posterior view of the dynamic spine stabilization system of FIG. **20**A implanted and extending between a vertebra of the spine and two adjacent vertebrae.

FIG. **22** is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **23** is a lateral view (in partial cross-section) of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **24**A is a lateral view (in partial cross-section) of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **24**B is a lateral view of the dynamic spine stabilization system of FIG. **24**A.

FIG. **25** is a posterior view of the dynamic spine stabilization system of FIG. **24**A implanted and extending between a vertebra of the spine and two adjacent vertebrae.

FIG. **26** is a lateral view of a further embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **27** is a lateral view of yet another embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **28** is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

FIG. **29** is a posterior view of an alternative embodiment of a dynamic spine stabilization system in accordance with the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Embodiments of the present invention include a system or implant and method that can dynamically stabilize the spine while providing for the preservation of spinal motion. Alternative embodiments can be used for spine fusion.

Embodiments of the invention include a construct with an anchoring system, a deflection rod system and a vertical rod system.

An advantage and aspect of some embodiments of anchoring systems in accordance with the present invention is that such embodiments include a head or saddle that allows for appropriate, efficient and convenient placement of the anchoring system relative to the spine in order to reduce the force that is placed on the anchoring system. Such embodiments have enhanced degrees of freedom which contribute to the ease of implantation of the anchor system and are designed to isolate the head from the rest of the dynamic stabilization system and the forces that the rest of the dynamic stabilization system can place on the anchor system and the anchor system/bone interface. Thus, the anchor system can provide a secure purchase in the spine.

An aspect and advantage of the invention is the ability to maximize the range of motion of the spine after embodiments of the dynamic stabilization, motion preservation implant of the invention are implanted in a patient. While traditional solutions to back pain include fusion, discectomy, and artificial implants that replace spine structure, embodiments of the present invention preserve the bone and ligament structure of the spine and preserve a wide range of motion of the spine, while stabilizing spines that were heretofore unstable due to degenerative and other spinal diseases.

Still another aspect of the invention is the preservation of the natural motion of the spine and the maintenance of the quality of motion as well as the wide range of motion so that the spine motion is as close to that of the natural spine as possible. The present embodiments of the invention allow for the selection of a less stiff, yet dynamically stable implant for use in a non-fusion situation. A less stiff, yet dynamically stable implant relates directly to a positive patient outcome, including patient comfort and the quality of motion of the spine.

In another aspect of the invention, load sharing is provided by embodiments, and, in particular, the deflection rod or loading rod of the embodiments. For embodiments of this invention, the terms "deflection rod" and "loading rod" can be used interchangeably. Accordingly this aspect of the invention is directed to restoring the normal motion of the spine. The embodiment provides stiffness and support where needed to support the loads exerted on the spine during normal spine motion, which loads, the soft tissues of the spine are no longer able to accommodate since these spine tissues are either degenerated or damaged. Load sharing is enhanced by the ability to select the appropriate stiffness of the deflection rod or loading rod in order to match the load sharing characteristics desired. By selecting the appropriate stiffness of the deflection rod or loading rod to match the physiology of the patient and the loads that the patient places on the spine, a better outcome is realized for the patient. Prior to implantation of the embodiment, the stiffness of the implant of the system can be selected among a number of loading rods. In other words, the stiffness is variable depending on the deflection rod or loading rod selected. In another aspect, the load sharing is between the spine and the embodiment of the invention.

As the load is carried along the deflection rod or loading rod, the embodiments of the invention can be made smaller in order to fit in more spaces relative to the spine.

An aspect of the invention is to preserve and not restrict motion between the vertebra of the spine through the use of appropriately selected vertical rods (and optionally horizontal rods) of embodiments of the invention.

Another aspect of the invention is the ability to control stiffness for extension, flexion, lateral bending and axial rotation, and to control stiffness for each of these motions independently of the other motions.

An aspect of the invention is to use the stiffness and load bearing characteristics of super elastic materials.

Another aspect of the invention is to use super elastic materials to customize the implant to the motion preservation and the dynamic stabilization needs of a patient. An aspect of such embodiments of the invention is to provide for a force plateau where motion of the implantation system continues without placement of additional force of the bone anchor system, or, in other words, the bone/implantation system interface.

Accordingly, an aspect of the invention is to be able to selectively vary the stiffness and selectively vary the orientation and direction that the stiffness is felt by varying the structure of the implantation system of the invention.

Another aspect of some embodiments of the invention is to prevent and/or provide for any off-axis implantation by allowing the implantation system to have enhanced degrees of freedom of placement of the implant.

A further aspect of embodiments of the invention is to control stabilized motion from micro-motion to broad extension, flexion, axial rotation, and lateral bending motions of the spine.

Yet another aspect of the embodiments of the invention is to be able to revise a dynamic stabilization implant should a fusion implant be indicated. This procedure can be accomplished by, for example, the removal of the deflection rod system of the implantation system and replacement with, for example, a stiffer deflection rod system. Accordingly, an aspect of the invention is to provide for a convenient path for a revision of the original implantation system, if needed.

A further aspect of the invention, due to the ease of implanting the anchoring system, is the ability to accommodate the bone structure of the spine, even if adjacent vertebra are misaligned with respect to each other.

A further aspect of the invention is that the implant is constructed around features of the spine such as the spinous processes and, thus, such features do not need to be removed and the implant does not get in the way of the normal motion of the spine features and the spine features do not get in the way of the operation of the implant.

Another aspect of embodiments of the invention is the ability to stabilize two, three and/or more levels of the spine by the selection of appropriate embodiments and components of embodiments of the invention for implantation in a patient. Further embodiments of the invention allow for fused levels to be placed next to dynamically stabilized levels. Such embodiments of the invention enable vertebral levels adjacent to fusion levels to be shielded by providing a more anatomical change from a rigid fusion level to a dynamically stable, motion preserved, and more mobile level.

Accordingly, another aspect of the embodiments of the invention is to provide a modular system that can be customized to the needs of the patient. A Deflection rod system can be selectively chosen for the particular patient as well the particular levels of the vertebrae of the spine that are treated. Further, the positioning of the embodiments of the invention can be selected to control stiffness and stability.

Another aspect of embodiments of the invention is that embodiments can be constructed to provide for higher stiffness and fusion at one level or to one portion of the spine while allowing for lower stiffness and dynamic stabilization at another adjacent level or to another portion of the spine.

Yet a further aspect of the invention is to provide for dynamic stabilization and motion preservation while preserving the bone and tissues of the spine in order to lessen trauma to the patient and to use the existing functional bone and tissue of the patient as optimally as possible in cooperation with embodiments of the invention.

Another object of the invention is to implant the embodiments of the invention in order to unload force from the spinal facets and other posterior spinal structures and also the intervertebral disc.

A further aspect of the invention is to implant the embodiment of the invention with a procedure that does not remove or alter bone or tear or sever tissue. In an aspect of the invention the muscle and other tissue can be urged out of the way during the inventive implantation procedure.

Accordingly, an aspect of the invention is to provide for a novel implantation procedure that is minimally invasive.

Dynamic Stabilization, Motion Preservation System for the Spine:

Common reference numerals are used throughout the drawings and detailed description to indicate like elements; therefore, reference numerals used in a drawing may or may not be referenced in the detailed description specific to such drawing if the associated element is described elsewhere. Further, the terms "vertical" and "horizontal" are used throughout the detailed description to describe general orientation of structures relative to the spine of a human patient that is standing.

FIG. **1**A is a posterior view (in partial cross-section) and FIG. **1**B is a lateral view of an embodiment of a deflection rod system implant **100** for use with dynamic stabilization, motion preservation systems (also referred to herein simply as "dynamic stabilization systems") in accordance with the present invention. The deflection rod system implant **100** comprises a deflection rod system or deflection rod system engine **110**, an anchoring device **102** and a vertical rod **120**. The deflection rod system **110** includes a deflection rod guide or shield **116** and a deflection rod **111** including an inner rod **112** within an outer shell **114**. The deflection rod **111** can have a varying diameter along its length. A decreasing diameter allows the deflection rods **111** to be more flexible and bendable along the length deflection rod length to more evenly distribute the load placed on the deflection rod system **100** by the spine. The outer shell **114** preferably is made of PEEK or other comparable polymer and has a diameter that continuously decreases along the length of the deflection rod **111**. The inner rod **112** can be comprised of a super elastic material. Preferably, the super elastic material is comprised of Nitinol (NiTi). In addition to Nitinol or nickel-titanium (NiTi), other super elastic materials include copper-zinc-aluminum and copper-aluminum-nickel. However, for biocompatibility, nickel-titanium is the preferred material. The inner rod **112**, like the overall deflection rod **111**, can vary in diameter and shape, although in a preferred embodiment, the inner rod **112** is substantially cylindrical.

Alternatively, the diameter of the outer shell **114** can decrease in discrete steps along the length of the distraction rod **111**, with the diameter of one step not being continuous with the diameter of the next adjacent step. Alternatively, for different force and load carrying criteria the diameters of the deflection rod can continuously increase in diameter or can have discreet step increases in diameter along the length of the deflection rod **111**. Still further, the deflection rod **111** can have at least one step of decreasing diameter and at least one step of increasing diameter in any order along the length of the deflection rod **111**, as desired for the force and load carrying characteristics of the deflection rod **111**.

The deflection rod **111** is arranged within the deflection rod guide or shield **116** which covers and, in this embodiment, substantially surrounds the deflection rod **111**. The deflection rod system **110** can be a preassembled unit provided to a surgeon for implantation by affixing the deflection rod system **110** to a bone (e.g., the pedicle of a vertebra) using an anchoring device **102** such as a bone screw. The deflection rod system **110** is connected with the anchoring device **102** by an arm **130**, which arm **130** can be integrally formed with the deflection rod system **110**, affixed to the deflection rod system **110** by one or more fasteners or fastening features (such as protruding structures that interlockingly engage each other when coupled), press fit to the deflection rod system **110**, or otherwise fixedly secured to the deflection rod system **110**. In the embodiment, the arm **130** includes an aperture **131** through which the anchoring device **102** is received and driven into the bone. The anchoring device **102** includes a head **104** that interferes with passage of the anchoring device **102** through the aperture **131**. Threads **106** of the anchoring device **102** grip the bone to hold the arm **130** between the bone and the head **104**, thereby affixing the arm **103** and by extension the deflection rod system **110** to the bone. Preferably, the anchoring device **102** is comprised of titanium; however, other biocompatible materials such as stainless steel and/or PEEK can be used. As will be appreciated upon reflecting on the different embodiments, the structures described herein can vary in size and shape based on factors such as material of construction, anatomical structure of the implantation site, implantation technique and targeted system performance (e.g., stiffness).

Referring to FIG. **2**, the vertical rod **120** is connected to the deflection rod **111** and can urge the deflection rod **111** in response to relative movement of two vertebrae between which the vertical rod **120** extends. In the embodiment shown, a distal end of the deflection rod **111** can be fixedly

mated with a spherical (or semi-spherical) ball or joint **118** that can pivot within a cradle at a proximal end of the vertical rod **120**. The vertical rod **120** can pivot in a posterior-to-anterior or anterior-to-posterior direction about the joint **118**, and optionally can pivot slightly in a lateral direction. The pivoting motion can allow adjustment of the vertical rod **120** relative to the deflection rod system **110** to ease manipulation of the dynamic stabilization system during implantation and optionally to reduce torque forces applied to the deflection rod **111**. A distal end of the vertical rod **120** can be fixedly connected with an upper (or lower) vertebra of the two vertebrae by an additional anchoring device **152**, such as a bone screw. The anchoring device **152** can include an arm **170** extending a clamp **162** that receives and secures the vertical rod **120**. The arm **170** extends laterally from the anchoring device **152** so that the anchoring device **152** can be positioned and secured to the upper pedicle **8** (a good source of bone for anchoring) while the clamp **162** can be aligned with the vertical rod **120** to receive the vertical rod **120**, which extends generally (though not necessarily) parallel to the spine. The dynamic stabilization system **100** comprises two substantially similar, mirrored structures connected at opposite pedicles **8**,**10** of the vertebrae **2**,**4**. However, in alternative embodiments, the dynamic stabilization system can comprise dissimilar structures, for example to accommodate anatomical asymmetry. FIG. **3**A illustrates an alternative embodiment wherein one or both of the deflection rod system arms **330** and clamp arm **370** can include a secondary aperture for receiving a locking screw **334**,**364** that can resist rotation of the corresponding arm. FIG. **3**B illustrates an alternative embodiment wherein the deflection rod system arm **330** includes a secondary aperture for receiving the locking screw **334**, and wherein the clamp and clamp arm are supplanted by an anchoring device **352** that receives the vertical rod **120** over a bone screw thread. The anchoring device **352** can resemble the anchoring device **752** shown in FIGS. **7**A, **7**B, and described below in the description of FIGS. **7**A, **7**B. Such anchoring devices can resemble anchoring devices described in U.S. Provisional Application 61/031,598, entitled "A DEFLECTION ROD SYSTEM FOR A DYNAMIC STABILIZATION AND MOTION PRESERVATION SPINAL IMPLANTATION SYSTEM AND METHOD" (SPART-01037US0), incorporated herein by reference. The alternative embodiment may reduce torque applied to the anchoring device **352** and simplify the anchoring device **352** to ease implantation of the anchoring device **352**.

More lateral placement of the vertical rods provides for more stiffness in lateral bending and an easier implant approach by, for example, a Wiltse approach as described in "The Paraspinal Sacraspinalis-Splitting Approach to the Lumber Spine," by Leon L. Wiltse et al., *The Journal of Bone & Joint Surgery*, Vol. 50-A, No. 5, July 1968, which is incorporated herein by reference.

The stiffness of the deflection rod system **100** can preferably be adjusted by the selection of the materials and placement and diameters of the deflection rod system as well as the horizontal and vertical rods. Larger diameter rods would increase the resistance of the deflection rod system **100** to flexion, extension rotation, and bending of the spine, while smaller diameter rods would decrease the resistance of the deflection rod system **100** to flexion, extension, rotation and bending of the spine. Further, continually or discretely changing the diameter of the deflection rods **111** along the length of the deflection rods **111** changes the stiffness characteristics. Thus, with the deflection rods **111** tapered toward the vertical rod **120**, the deflection rod system **100** can have more flexibility in flexion and extension of the spine. Further, using a super elastic material for the vertical rod **120** in addition to the deflection rod **111** adds to the flexibility of the deflection rod system **100**. Further, the vertical rods **120**, in addition to the deflection rods **111**, can be made of titanium or stainless steel or PEEK should a stiffer deflection rod system **100** be required. Thus, it can be appreciated that the deflection rod system **100** can selectively accommodate the desired stiffness for the patient depending on the materials uses, and the diameter of the materials, and the placement of the elements of the deflection rod system **100**.

Should an implanted deflection rod system **100** need to be revised, that can be accomplished by removing and replacing the vertical rod **120** and/or deflection rod system **110** to obtain the desired stiffness. By way of example only, should a stiffer revised deflection rod system **100** be desired, more akin to a fusion, or, in fact, a fusion, then the deflection rod system **110** having the deflection rods **111** can be removed and replaced by a deflection rod system **110** having the deflection rods **111** made of titanium, or stainless steel, or non-super elastic rods to increase the stiffness of the system. This can be accomplished in some embodiments described herein by leaving the anchoring device **102** in place and removing the existing deflection rod systems **110** and replacing the deflection rod systems with deflection rod systems having stiffer distraction rods **111** and outer shells and associated vertical rods **120**.

In alternative embodiments of methods of stabilizing vertebral motion segments in accordance with the present invention, the dynamic stabilization system **100** can be implanted in an arrangement vertically flipped from the arrangement of FIG. **2**. As shown in FIG. **4**, the deflection rod system **110** is fixedly connected with the upper vertebra by the anchoring system **102**. The vertical rod **120** is connected to the deflection rod **111** and extends caudally to the lower vertebra. The vertical rod **102** urges the deflection rod **111** in response to relative movement of the two vertebrae between which the vertical rod **120** extends. As with the previously described arrangement and as shown in FIG. **5**, one or both of the deflection rod system arms **330** and clamp arms **370** can include a secondary aperture for receiving a locking screw **334**, **364** that can resist rotation of the corresponding arm. Referring to FIG. **6**, in still further embodiments, one or both of the deflection rod system arms **630** and clamp arms **670** can be adapted to connect with horizontal rods **680**, **682** that extend between pedicles **8**,**10** of a vertebra. The anchoring devices **602**, **652** can include a U-shaped channel for receiving the horizontal rod **680**, **682**, the horizontal rod being held in the channel by a locking set screw **644**, **654**. The horizontal rods **680**, **682** are positioned between adjacent spinous processes **2**, **4** associated with the vertebrae and can pierce or displace the interspinal ligament without severing or removing tissue. The horizontal rods **680**, **682** can resist rotation and can be used in place of locking screws. In a preferred embodiment, the horizontal rod **680**,**682** can be comprised of titanium, stainless steel or PEEK or another biocompatible material, and the first and second deflection rods or loading rods can be comprised of a super elastic material. Preferably, the super elastic material is comprised of Nitinol (NiTi). In addition to Nitinol or nickel-titanium (NiTi), other super elastic materials include copper-zinc-aluminum and copper-aluminum-nickel. However, for biocompatibility, the nickel-titanium is the preferred material.

FIGS. **7**A-**9** illustrate a still further embodiment of a deflection rod system **700** in accordance with the present invention comprising an deflection rod system **710** connectable with an anchoring device **702** after the anchoring device **702** is secured to a pedicle. Such embodiments can reduce visual obstruction of the pedicle during seating of the anchor-

ing device **702** by reducing the size of the structure seated. An anchoring block **732** receives the anchoring device **702** through an aperture **731** and is secured to the pedicle as threads **106** of the anchoring device **702** grip the bone and the head **704** is seated within the anchoring block **732**. The anchoring block **732** includes an internal screw thread **734** through at least a portion of the anchoring block **732** for receiving a screw **742** to secure an deflection rod system arm **730** of the deflection rod system **710**. As in previous embodiments, the deflection rod system **710** comprises a deflection rod shield or guide **716** and a deflection rod **711** including an inner rod (not visible) within an outer shell **714**. As shown, the deflection rod system **710** is connected with an arm **730** having a curved base that meets a curved surface of the anchoring block **732** (FIG. **7**C). The arm **730** can pivot slightly relative to the anchoring device **702**, allowing the surgeon to adjust an angle of protrusion of the deflection rod system **710** relative to the spine. The arm **730** is fastened to the anchoring block **732** by the screw **742** which is connected through a spacer **744** having a surface in sliding contact with a curved surface of the arm **730** to distribute force generally evenly along the arm **730** when arranged at a desired orientation. In this arrangement, preferably, the joint **718** is adjacent with and located over the anchor **702** in order to minimize or eliminate the transfer of torque forces from the rod **720** to the anchor **702**. Other complementary mating surfaces may be used to obtain the desired relative motion.

A vertical rod **720** is connected to the deflection rod **711** and can urge the deflection rod **711** in response to relative movement of two vertebrae between which the vertical rod **720** extends. A distal end of the deflection rod **711** can be fixedly mated with a spherical (or semi-spherical) ball or joint **718** that can pivot within a cradle at a proximal end of the vertical rod **720**. The vertical rod **720** can pivot in a posterior-to-anterior or anterior-to-posterior direction about the joint **718**, and optionally can pivot in a lateral direction. The pivoting motion can allow adjustment of the vertical rod **720** relative to the deflection rod system **710** to ease manipulation of the dynamic stabilization system during implantation and optionally to reduce torque forces applied to the deflection rod **711**. A distal end of the vertical rod **720** can be fixedly connected with an upper or lower vertebra of the two vertebrae by an additional anchoring device **752**. The anchoring device can resemble anchoring devices as described in U.S. Provisional Application No. 61/031,598. As shown, the anchoring device **752** includes a saddle **758** that can receive the vertical rod **720**. A locking set screw **754** can be urged along threads of the saddle **758** so that the locking set screw **754** secures the vertical rod **758** against the U-shaped channel of the saddle **758**. A bone screw thread **756** can optionally be mated with a body of the anchoring device **752** by a fastener **772** that permits at least cranial-to-caudal pivoting. The saddle **758** can include a hex-shaped outer surface to assist in seating the bone screw **756** within the upper pedicle **8**. As shown in FIGS. **8** and **9**, the deflection rod system **700** can be arranged with the deflection rod system **710** anchored to an upper of two vertebrae, or alternatively, the lower of two vertebrae.

FIG. **10** is a posterior view of a still further embodiment of a deflection rod system implant **1000** in accordance with the present invention comprising an deflection rod system **610** that is engaged during spine extension, but not engaged during spine flexion. The deflection rod system **610** and associated structures resemble the deflection rod system and associated structures of FIG. **6**, and can be connected with a horizontal rod **680** extending between pedicles of a vertebra. A vertical rod **1020** is connected at a proximal end to a deflection rod **111** of the deflection rod system **610**. The distal end of the vertical rod **1010** is unattached and slides within a boot **1090**. The boot **1090** blocks movement of the vertical rod **1020** when the distal end of the vertical rod **1020** abuts the base of the boot **1090**, and further extension movement will cause the vertical rod **1020** to deflect the deflection rod **111**. The boot **1090** is preferably sized to accommodate movement of vertical rod **1020** within the boot **1090** that spans a length of natural movement of the spine during extension, to avoid separation of the vertical rod **1020** from the boot **1090**. Alternatively, the distal end of the vertical rod can include a ball or other slidable structure that is held within a cavity of the boot, enabling the boot to resist both extension and flexion, and to permit a range of free motion determined by the surgeon. As shown, the boot **1090** is connected with an anchoring device **1052** by an arm **1070**. A locking screw **1062** resists rotation of the boot **1090** about the anchoring device **1052** in response to a force applied by the vertical rod **1020**.

FIG. **11**A is a posterior view (in partial cross-section) and FIG. **11**B is a lateral view (in partial cross-section) of a still further embodiment of a deflection rod system implant **1100** for use with dynamic stabilization systems accordance with the present invention. The deflection rod system implant **1100** is adapted to support multiple motion segments and comprises a first deflection rod system **1110***a* connected with a vertical rod **1120***a* extending cranially, a second deflection rod system **1110***b* connected with a vertical rod **1120***b* extending caudally, and an anchoring device **1102**. The first and second deflection rod systems **1110***a*, **1110***b* can have similar or different bending or load carrying or stiffness characteristics, as prescribed by the surgeon or a physician. A common arm **1130** connects the first and second deflection rod systems **1110***a*, **1110***b* with the anchoring device **1102**. The arm **1130** includes an aperture **1131** through which the anchoring device **1102** is received and driven into the bone. The anchoring device **1102** includes a head **1104** that interferes with passage of the anchoring device **1102** through the aperture **1131**. Threads **1106** of the anchoring device **1102** grip the bone to hold the arm **1130** between the bone and the head **1104**, thereby affixing the arm **1103** and by extension the deflection rod systems **1110***a*, **1110***b*. The arm **1130** can be adapted to connect with a horizontal rod **1180** that extend between pedicles **10** of a vertebra. The horizontal rod **1180** can be received in U-shaped slots of the arm **1130** and urged against the head **1104** of the anchoring device **1102** by a locking set screw **1144** having external threads that mate with internal threads of the walls of the arm channel.

FIG. **12** is a lateral view of a deflection rod system implant **1200** resembling the deflection rod system implant **1100** of FIG. **11**B with a compressor element or cradle **1236** positioned within the channel and between the horizontal rod **1180** and anchoring device **1202**. As shown, the head **1204** of the anchoring device **1202** has a spherical or semi-spherical shape, although alternatively the head can have some other shape that complements the compressor element or cradle **1236** while permitted at least limited movement between the two structures to allow flexibility in relative arrangement during implantation. For example, the head can have a rounded indention mateable with a spherical surface.

The compressor element or cradle **1236** has a generally cylindrical body so that the compressor element **1236** can fit within a bore of the arm **1230**. A posterior surface of the compressor element **1236** is concave and generally complementing the horizontal rod **1180** which rests thereon. The anterior surface of the compressor **1236** is in sliding contact with the head **1204** to allow the anchoring device **1202** to be positioned as appropriate. The locking set screw **1144** urges

the horizontal rod **1180** against the compressor element **1236**, which in turn is urged against the anchoring device **1202**. Alternatively, the compressor element **1236** and head **1204** can have some other complementary shape that allows some or no sliding contact between the structures.

FIG. **13** is a posterior view of the deflection rod system implant **1200** of FIG. **11** comprising the first deflection rod system **1110***a* and second deflection rod system **1110***b* secured to a vertebra common to two adjacent motion segments targeted for stabilization by an anchoring device **1102**. A first vertical rod **1120***a* is connected to a deflection rod **1111***a* of the first deflection rod system **1110***a* and extends cranially to the upper vertebra of the upper targeted motion segment, and is secured to the upper vertebra by a clamp **162**. A second vertical rod **1120***b* is connected to a deflection rod **1111***b* of the second deflection rod system **1110***b* and extends caudally to the lower vertebra of the lower targeted motion segment, and is secured to the lower vertebra by a clamp **162**. The vertical rods **1120***a*, **1120***b* urge respective deflection rods **1111***a*,**1111***b* in response to relative movement of the two vertebrae between which the vertical rods **1120***a*,**1120***b* extend. Preferably, vertical rod **1120***a* is aligned with vertical rod **1120***b* in order to reduce or eliminate torque forces. An arm **1130** common to the deflection rod systems **1110***a*,**1110***b* is connected with a horizontal rod **1180** that extends between pedicles of the common vertebra to a complementary pair of deflection rod systems. The horizontal rod **1180** is positioned between adjacent spinous processes **2**,**4** associated with the vertebrae and can pierce or displace the interspinal ligament without severing or removing tissue. The horizontal rod **1180** can resist rotation of the deflection rod systems **1110***a*,**1110***b* and can be used in place of locking screws.

FIGS. **14**A and **14**B illustrate yet another embodiment of a deflection rod system implant **1400** in accordance with the present invention comprising an deflection rod system **1410** connectable with an anchoring device **1402**, preferably after the anchoring device **1402** is secured to a pedicle. An arm **1430** of the deflection rod system **1410** comprises a collar **1464** that can be received over a head **1404** of the anchoring device **1402** to capture a horizontal bar **1480**. The arm **1430** can be secured to the head **1404** by a collar screw **1450**. The horizontal bar **1480** can be held in place by one or both of the arm **1430** which is urged against the horizontal bar **1480** by the collar screw **1450**, and a locking set screw **1458**. Optionally, the head **1404** of the anchoring device can be connected with a yoke **1407** by a pin **1403** to allow the head **1404** to be pivoted during implantation. Such an arrangement can allow a thread **106** of the anchoring device **1402** to be seated within the pedicle at an acute angle relative to a plane of the collar.

Referring to FIG. **15**, the deflection rod system implant **1400** of FIGS. **14**A and **14**B is shown implanted between two vertebrae to stabilize the motion segment associated with the vertebrae. The deflection rod system **1410** is anchored to the upper vertebra of the motion segment and a vertical rod **120** is connected between a deflection rod **111** of the deflection rod system **1410** and a clamp **162** connected with the lower vertebra by an anchoring device **152**. FIG. **16** is a posterior view of a still further embodiment of a deflection rod system implant **1600** in accordance with the present invention comprising an deflection rod system **1610** connected with an arm **1630** that resembles the arm **1430** of FIG. **14**A-**15**; however, the deflection rod system **1610** is connected with the arm **1630** so that the deflection rod **111** extends toward the spinous process **2** rather than away from the spinous process (i.e., the deflection rod system **1610** is "inboard). The clamp **162** is connected with the anchoring device **152** by a clamp arm **1670** that likewise extends toward a spinous process **4**.

The embodiments described above comprise deflection rods extending generally in a transverse direction to the orientation of the bone anchor screw. In still other embodiments, deflection rod systems can be oriented generally in a co-axial or collinear or parallel orientation to a bone anchor screw. Referring to FIGS. **17**-**22**, the deflection rod system can extend substantially co-axial or parallel to the threaded shaft of an anchoring device. As will be appreciated upon reflecting on the teaching provided herein, such embodiments can simplify implantation, reduce trauma to structures surrounding an implantation site, and reduce system components.

FIG. **17** illustrates an embodiment of a deflection rod system implant **1700** comprising an anchoring device **1702** with a cavity **1709** for receiving a deflection rod system **1710**. It has been observed that acceptable anchoring can be achieved in a bone such as a pedicle using a thread **1706** pattern that include deep threads **1706***x* (i.e., having a maximum difference between inner diameter, $D_I$, and outer diameter, $D_O$, of a shaft of the anchoring device) nearer the distal end of the shaft and comparatively shallow threads **1706***y* nearer the shank **1705**. The comparatively shallow threads **1706***y* can enable a larger inner diameter, $D_{I2}$, of the anchoring device **1702** shaft which can accommodate the deflection rod system **1710**. In some embodiments, the cavity can have a size and shape that can accommodate deflection rod systems having a range of different performance characteristics (e.g., stiffness, range of motion). A physician or surgeon can implant an anchoring device **1702** selected independently from the deflection rod system **1710** and based on the anatomy into which it is implanted. For example, the anchoring device **1702** can be selected based on the location of the vertebrae (e.g., L5-S1 vs. C7-T1) or the age and sex of the patient. The deflection rod system **1710** can then be selected based on the desired performance characteristics. The deflection rod system **1710** can be seated within the cavity using myriad different techniques. For example, the distraction rod guide or shield **1716** can be press fit into the walls of the cavity **1709**, or the distraction rod guide **1716** can be cemented or otherwise adhesively fixed to the walls of the cavity **1709**. Alternatively, the distraction rod guide or shield **1716** can be captured in the cavity **1709** by a locking set screw or ratchet feature. Further, the distraction rod guide **1716** (and deflection rod system **1710**) can have a length longer than that of the cavity **1709** so that a portion of the distraction rod guide **1716** extends outside of the cavity **1702** and posterior to the anchoring device **1702**. One of ordinary skill in the art, upon reflecting on the teachings provided herein, will appreciate the myriad ways in which the deflection rod system **1710** can be fixedly associated with an anchoring device **1702**.

The distraction rod system **1700** of FIG. **17** generally includes less, or simpler footprint than the previously described embodiments, potentially reducing the amount of displacement of tissue and/or bone, reducing trauma to tissue and/or bone during surgery. Further, the smaller footprint can reduce the amount of tissue that needs to be exposed during implantation. Still further, arranging the deflection rod system **1710** co-axial with a shaft of the anchoring device **1702** can substantially transfer a moment force applied by the deflection rod system **1710** from a moment force tending to pivot or rotate the anchoring device **1702** about the axis of the shaft, to a moment force tending to act perpendicular to the axis of the shaft. The distraction rod system implant **1700** can effectively resist repositioning of the deflection rod system **1710** and/or anchoring device **1702** without the use of locking screws or horizontal bars to resist rotation. Eliminating locking screws and/or horizontal bars can reduce exposure of tissue and/or bone to foreign bodies.

FIG. **18** illustrates an alternative embodiment of a deflection rod system implant **1800** comprising an anchoring device **1802** with a cavity **1809** for receiving a distraction rod **111**. The embodiment resembles the deflection rod system **1700** of FIG. **17**; however, the distraction rod guide or shield **1816** is integrally formed in a shank **1805** of the anchoring device **1802**. The distraction rod guide or shield **1816** can be sized and shaped to provide, in combination with the choice of inner rod **112** and outer shell **114**, a desired performance characteristic. Integrally forming the distraction rod guide **1816** in a shank **1805** of the anchoring device **1802** can potentially reduce a thickness otherwise required to accommodate separate components. The distraction rod **111** can be mated with the distraction rod guide **1816** applying similar techniques to mate distraction rods within previously described distraction rod guide or shield.

FIG. **19** illustrates a still further embodiment of a deflection rod system implant **1900** comprising an anchoring device **1902** with a cavity **1909** including inner threads for receiving an deflection rod system screw **1913**, with complementary external threads extending from an deflection rod system **1910**. The deflection rod system screw **1913** provides easy mating of the deflection rod system **1910** with the anchoring device **1902**. The deflection rod system **1910** can further include a spherical (or semi-spherical) ball or joint **1918** that allows pivoting of a vertical rod **1920** connected with the deflection rod system **1910** so that the vertical rod **1920** can be oriented in a needed direction as the deflection rod system **1910** is rotated and the deflection rod system screw **1913** is seated within the cavity **1909**. The vertical rod **1920** can then be pivoted into place extending between pedicles. The embodiment of FIG. **19** can simplify and shorten surgery by providing an easy technique for implanting the deflection rod system **1910**.

FIGS. **20**A and **20**B illustrate yet another embodiment of a deflection rod system implant **2000** in accordance with the present invention comprising an anchoring device **2002** with a housing **2009** for receiving a deflection rod system **2010**. The embodiment resembles the deflection rod system implant **1700** of FIG. **17**; however, housing **2009** is connected with the anchoring device **2002** at the shank **2005**, but is not formed in the shank **2005**. Depending on the outer diameter of the housing **2009** and the inner diameter of the cavity that receives the deflection rod system **2010**, the housing **2009** permits use of one or both of (1) a threaded shaft **2006** having a smaller diameter (for example for use in smaller bones, such as in the cervical region) and (2) a deflection rod system **2010** comprising a deflection rod guide shield **2016** with a larger diameter (e.g., for use with thicker (and stiffer) deflection rods). As shown, the housing **2009** further comprises a threaded screw hole **2057** extending along an axis at an acute angle to the axis of the threaded shaft. The threaded screw hole **2057** receives a locking set screw **2058** that when seated (FIG. **20**B) protrudes into the housing **2009** or against the deflection rod system **2010**, where the deflection rod system **2010** is seated within the housing **2009**. The locking set screw **2058** holds the deflection rod system **2018** in place within the housing **2009**. In this embodiment, a deflection rod system **2010** can be selected to have an appropriate stiffness for the patient. Further, if several deflection rod system implants **2000** are used in a patient, each deflection rod system **2010**, if desired, can have a different stiffness.

FIG. **21** is a posterior view of the deflection rod system implant **2000** of FIGS. **20**A and **20**B implanted between pedicles **8**,**10** of adjacent vertebrae of a targeted motion segment. As shown, both ends of a vertical rod **2020** connected with the deflection rod system implant **2000** is connected with an deflection rod system **2010**, in contrast to previous figures. Alternatively, one end of the vertical rod **2020** can be connected with an anchoring device such as described above, for example in FIG. **9**. As will be appreciated, the deflection rod system implant **2000** has a small footprint from a posterior perspective.

FIG. **22** is a posterior view of still another embodiment of a deflection rod system implant **2200** in accordance with the present invention adapted to support multiple motion segments. An anchoring device **2202** resembles the anchoring devices of FIGS. **17**-**20**B and includes an outer wall **2203** having a hex portion for gripping using a torque wrench or other tool during implantation of the anchoring device **2202** in a bone. An anchoring device **2202** is secured to the two pedicles **10** of a vertebra common to the two motion segments to be supported. A vertical rod **2220** connected with an deflection rod system **2210** mated with the anchoring device **2202**, extends between the vertebra and an upper vertebra of the upper motion segment, and is connected to a pedicle **8** of the segment by an upper anchoring device **752**. As above, the vertical rod **2220** is connected to the deflection rod and can deflect the deflection rod in response to relative movement of two vertebrae between which the vertical rod **2220** extends. Another vertical rod **2222** includes a yolk **2223** resembling a box-end wrench with a shape generally complementing the hex pattern of the outer wall of the bone anchor. The yolk **2223** is received over the outer wall **2203** of the anchoring device **2202**, and can resist rotation the vertical rod **2222** relative to the anchoring device **2202**. The vertical rod **2222** extends to the lower vertebra of the lower motion segment, and is connected to a pedicle **12** of the motion segment by a lower anchoring device **752**. The vertical rod **2222** can resist movement between vertebrae **4** and **6**, and thus supplement or substitute for other fusion devices, for example.

FIG. **23** is a lateral view (in partial cross-section) of an alternative embodiment of a deflection rod system implant **2300** for use with dynamic stabilization systems in accordance with the present invention and adapted to dynamically support multiple motion segments of the spine. The deflection rod system implant **2300** resembles the deflection rod system implant **1100** of FIG. **11**A, but includes deflection rod systems generally oriented in an anterior-to-posterior direction. The deflection rod system implant **2300** is adapted to support multiple motion segments and comprises a first deflection rod system **2310***a* connected with a vertical rod **120***a* extending cranially, a second deflection rod system **2310***b* connected with a vertical rod **120***b* extending caudally, and an anchoring device **2302**. The first and second deflection rod systems **2310***a*, **2310***b* can have similar or different bending characteristics, as prescribed by the surgeon or a physician. A common arm **2330** connects the first and second deflection rod systems **2310***a*, **2310***b* with the anchoring device **2302**. The orientation of the deflection rod systems **2310***a*, **2310***b* can reduce the moment force that tends to cause rotation of the arm **2330**; however, in other embodiments it may be desirable to include a head capable of receiving a horizontal rod to further resist moment force. In this embodiment, the deflection rod systems **2310***a*, **2310***b* are substantially parallel.

FIG. **24**A is a lateral view (in partial cross-section) and FIG. **24**B is a cranial view (in partial cross-section) of still another embodiment of a deflection rod system implant **2400** for use with dynamic stabilization systems accordance with the present invention and adapted to dynamically support multiple motion segments is shown. The deflection rod system implant **2400** resembles the deflection rod system implant **2300** of FIG. **23**. An arm **2430** that is mated with the anchoring device **2402** after the anchoring device **2402** has

been implanted within a bone. The arm **2430** receives a locking screw **2440** having threads that complement threads of a screw hole within the head **2404** of the anchoring device **2402**. The locking screw **2440** fixedly connects the arm **2430** to the anchoring device **2402** when the locking screw **2440** is seated within the head **2404**. The embodiment also includes a distraction rod guide or shield **2416** integrally formed with the arm **2430**. In this embodiment, the deflection rod systems **2410** are substantially parallel. As seen in FIGS. **24**A, **24**B the arm **2430** can connect to the head **2404** in a number of orientations. This can be accomplished with an arm **2430** with a convex surface that mates with a concave surface of the head **2404** as shown, by way of example only, as depicted in FIG. **7**C.

FIG. **25** is a posterior view of the deflection rod system implant **2300** of FIG. **23** comprising the first deflection rod system **2310***a* and second deflection rod system **2310***b* secured to a vertebra common to two adjacent motion segments or vertebrae targeted for stabilization by an anchoring device. A first vertical rod **2320***a* is connected to a deflection rod **2311***a* of the first deflection rod system **2310***a* and extends cranially to the upper vertebra of the upper targeted motion segment, and is secured to the upper vertebra by an upper anchoring device **752**. A second vertical rod **2320***b* is connected to a deflection rod **2311***b* of the second deflection rod system **2310***b* and extends caudally to the lower vertebra of the lower targeted motion segment, and is secured to the lower vertebra by a lower anchoring device **752**. The vertical rods **2320***a*, **2310***b* deflect respective deflection rods **2311***a*, **2311***b* in response to relative movement of the two vertebrae between which the vertical rods **2320***a*, **2320***b* extend.

FIG. **26** illustrates an embodiment of a deflection rod system implant **2600** comprising an anchoring device **2602** with a cavity **2609** for receiving a deflection rod system **2610**. As mentioned above, it has been observed that acceptable anchoring can be achieved in a bone such as a pedicle using a thread **2606** pattern that include deep threads **2606***y* and shallow threads **2606***x*. The anchoring device **2602** can have a length such that when implanted a portion of the anchoring device **2602** further from the deflection rod system **2610** is seated within cancellous bone while a portion of the anchoring device **2602** nearer the deflection rod system **2610** is seated within cortical bone. Screw threads **2606***x* having a high pitch (i.e., having a comparatively large gap between threads) and deep threads are usable with satisfactory results in cancellous bone, which bone is an osseous tissue with a low density strength but high surface area. Screw threads **2606***y* having a low pitch and shallow threads are usable with satisfactory results in cortical bone, which bone is an osseous tissue with a high density strength. The diameter, $D_{12}$, of the anchoring device shaft can be expanded along a portion of the shaft that is seated within the cortical bone and/or a portion of the shaft that accommodates the deflection rod system **2610**. Expanding the diameter of the shaft can allow the threads to cut new thread patterns within the cortical bone, and can accommodate a deflection rod system **2610** (or range of deflection rod systems) having a larger diameter. Further, the diameter of the shaft can be larger where the cortical threads are shallow, as the vertebral bone is thicker in this area. For the same reason, the corresponding diameter of the bone as shown in FIG. **27** can be larger.

FIG. **27** illustrates a still further embodiment of a deflection rod system implant **2700** comprising an anchoring device **2702** including an external thread pattern resembling the external thread pattern of FIG. **26**, and further including a cavity **2709** with inner threads for receiving an deflection rod system screw **1913**, with complementary external threads extending from an deflection rod system **1910**. The deflection rod system screw **1913** provides easy mating of the deflection rod system **1910** with the anchoring device **1902**. The deflection rod system **1910** can further include a spherical (or semi-spherical) ball or joint **1918** that allows pivoting of a vertical rod **1920** connected with the deflection rod system **1910** so that the vertical rod **1920** can be oriented in a needed direction as the deflection rod system **1910** is rotated and the deflection rod system screw **1913** is seated within the cavity **1909**. The vertical rod **1920** can then be pivoted into place extending between pedicles.

Referring again to FIG. **22**, multiple motion segments can be stabilized by stringing together vertical rods and deflection rod systems individually selected for the corresponding motion segment. As shown in FIG. **22**, the yoke **2223** of a vertical rod **2222** is fitted over the outer wall **2203** of a deflection rod system **2210**. An opposite end of the vertical rod **2222** is connected to an anchoring device **2202**. However, in still other embodiment (as shown in FIG. **28**), the vertical rod **2822** can be connected with a second deflection rod system **2810***b* anchored by an anchoring device **2802***b* to a pedicle **12** of a lower vertebra of the motion segment. The deflection rod system **2810***b* allows controlled relative movement of the two vertebrae. Systems and methods in accordance with the present invention can comprise a series of implants connected with, and selected for the corresponding motion segment. The implants can comprise vertical rods rigidly connected between vertebrae as shown in FIG. **22** (for example to support fusion), or alternatively the vertical rods can be dynamically connected between vertebrae by a deflection rod system as shown in FIG. **28**. Any combination of implants can be used having a stiffness selected for the respective motion segment. For example, FIG. **29** illustrates dynamic stabilization of three motion segments with two yoked vertical rods **2922***a*, **2922***b* fitted over dynamic stabilization systems **2810***a*, **2810***b* anchored at an upper vertebra of the targeted segment.

While the vertical rods **2822**, **2922** of FIGS. **28** and **29** are shown to be connected with dynamic stabilization systems implanted in respective pedicles, embodiments of systems and methods can comprise vertical rods that are connected with dynamic stabilization systems after implantation of dynamic stabilization systems. The vertical rods **2822**, **2922** can be attachable with a dynamic stabilization system at or near the connection with the spherical ball joint. Such an arrangement can allow a yoke of a vertical rod to be placed over and around the outer wall of a dynamic stabilization system (or simply past the spherical ball joint in a staging position for further adjustment) without interference from the vertical rod of that dynamic stabilization system.

It is proposed that a preferred embodiment may have the following preferred dimensions, although dimension can vary substantially based on a number of performance factors.

- Inner rod having a diameter of about 0.080 inches.
- Outer shell having a major diameter of about 165 inches and the tapered portion tapers at about 2.5 degrees per side.
- Shield and deflection guide having a housing diameter of about 0.265 inches.
- The deflection rod is secured to the deflection guide along a length of about 0.200 inches from the end of the deflection rod system.
- The deflection rod system has a working length from the end of the system to the center of the ball joint of about 1.040 less the press fit length of about 0.200 which is length of about 0.840.

The overall length of the deflection rod system is about 1.100 inches.

The spherical ball in the ball and socket joint that secures the vertical rod to the deflection rod system has a diameter of about 188 inches.

The vertical rod has a diameter of about 0.150 inches.

Materials of Embodiments of the Invention:

In addition to Nitinol or nickel-titanium (NiTi) other super elastic materials include copper-zinc-aluminum and copper-aluminum-nickel. However for biocompatibility the nickel-titanium is the preferred material.

As desired, the implant can, in part, be made of titanium or stainless steel. Other suitable material includes by way of example only polyetheretherketone (PEEK), polyetherketoneketone (PEKK), polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK). Still, more specifically, the material can be PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

As will be appreciated by those of skill in the art, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention.

Reference to appropriate polymers that can be used in the spacer can be made to the following documents. These documents include: PCT Publication WO 02/02158 A1, dated Jan. 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated Jan. 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and PCT Publication WO 02/00270 A1, dated Jan. 3, 2002, entitled "Bio-Compatible Polymeric Materials."

The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims and their equivalents.

What is claimed is:

**1**. A deflection rod system adapted to be mounted to a bone anchor implanted in a spine, the deflection rod system comprising:

a shield having a shield cavity having a shield cavity axis;

a deflectable rod having a proximal end and a distal end, the deflectable rod being disposed in the shield cavity aligned with the shield cavity axis such that the proximal end extends out of the shield cavity and the distal end is connected to said shield;

wherein a proximal portion of the deflectable rod is spaced from the shield within the shield cavity such that the proximal portion of the deflection rod can deflect within said shield cavity transverse to the shield cavity axis thereby permitting the proximal end of the deflection rod to deflect;

a connector rod that is attached to said proximal end of said deflectable rod with a connector; and

a mount connected to said shield that mounts said deflection rod system relative to said bone anchor in one of a plurality of positions.

**2**. The deflection rod system of claim **1** wherein said connector is adapted to be mounted in-line with the bone anchor so as to minimize any torque that said connector rod can place on the bone anchor.

**3**. The deflection rod system of claim **1** wherein the bone anchor includes a bone anchor head and said mount is adapted to mount said deflection rod system relative to said bone anchor head in one said plurality of positions.

**4**. The deflection rod system of claim **1** wherein the bone anchor includes a curved anchor surface and wherein said mount includes a curved mount surface adapted to be mated with the curved anchor surface with the curved mount surface moveable relative to said curved anchor surface.

**5**. The deflection rod system of claim **1** wherein said deflectable rod includes an inner rod and an outer shell positioned about said inner rod.

**6**. The deflection rod system of claim **1** wherein said deflectable rod comprises a super elastic material.

**7**. The deflection rod system of claim **1** wherein said connector permits movement between said connector rod and said deflectable rod.

**8**. The deflection rod system of claim **1** wherein said mount mounts said deflection rod system such that the shield cavity axis is oriented about transverse to the bone anchor.

**9**. The deflection rod system of claim **1** wherein said mount mounts said deflectable rod about perpendicular to said connector in a first position and said mount allows said connector and said deflectable rod to move relative to each other from said first position.

**10**. The deflection rod system of claim **5** wherein said inner rod has a proximal end that extends from said outer shell and from said shield, and said connector is connected to said proximal end of said inner rod.

**11**. A deflection rod system adapted to be mounted to a bone anchor which is implanted in a spine wherein the deflection rod system comprises:

a shield having a shield cavity having a shield cavity axis;

a deflectable rod having a proximal end and a distal end, the deflectable rod being disposed in the shield cavity aligned with the shield cavity axis such that the proximal end extends out of the shield cavity and the distal end is connected to said shield;

wherein a proximal portion of the deflectable rod is spaced from the shield within the shield cavity such that the proximal portion of the deflection rod can deflect within said shield cavity transverse to the shield cavity axis thereby permitting the proximal end of the deflection rod to deflect;

a connector rod that is attached to said proximal end of said deflectable rod with a connector;

said shield including a mount that is adapted to mount to said deflection rod relative to the bone anchor in one of a plurality of positions; and

wherein the bone anchor includes a curved anchor surface and wherein said mount includes a curved mount surface adapted to be mated with the curved anchor surface with the curved mount surface moveable relative to said curved anchor surface.

**12**. The deflection rod system of claim **11** wherein said connector is adapted to be mounted in-line with the bone anchor so as to minimize any torque that said connector rod can place on the bone anchor.

13. The deflection rod system of claim 11 wherein said mount is adapted to mount said deflection rod system about transverse to the bone anchor.

14. The deflection rod system of claim 11 wherein said deflectable rod includes an inner rod and an outer shell positioned about said inner rod.

15. The deflection rod system of claim 11 wherein said deflectable rod comprises a super elastic material.

16. The deflection rod system of claim 11 wherein said connector is a ball and socket connector and said ball and socket connector is adapted to be positioned in-line with the bone anchor.

17. A deflection rod system adapted to be mounted to a bone anchor implanted in a spine, the deflection rod system comprising:

a shield having a shield cavity having a shield cavity axis;

a deflectable rod having a proximal end and a distal end, the deflectable rod being disposed in the shield cavity aligned with the shield cavity axis such that the proximal end extends out of the shield cavity and the distal end is connected to said shield;

wherein a proximal portion of the deflectable rod is spaced from the shield within the shield cavity such that the proximal portion of the deflection rod can deflect within said shield cavity transverse to the shield cavity axis thereby permitting the proximal end of the deflection rod to deflect;

a connector rod that is attached to said proximal end of said deflectable rod with a connector;

a mount connected to said shield that is adapted to mount said deflection rod system relative to a bone anchor in one of a plurality of positions;

wherein said bone anchor includes a curved anchor surface and said mount includes a curved mount surface adapted to mate with the curved anchor surface with the curved mount surface moveable relative to said curved anchor surface;

wherein said connector is adapted to be mounted in-line with the bone anchor so as to minimize any torque that said connector rod can place on the bone anchor; and

wherein said mount is adapted to mount said deflection rod system such that the shield cavity axis is about transverse to the bone anchor.

18. The deflection rod system of claim 17, wherein said deflectable rod includes an inner rod and an outer shell positioned about said inner rod, and said inner rod comprises a super elastic material.

19. The deflection rod system of claim 17, wherein said connector is a ball and socket connector, and said ball and socket connector is positioned in-line with the bone anchor.

20. The deflection rod system of claim 17, wherein said connector permits movement between said connector rod and said deflectable rod.

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